IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO ALL
WAVE ONE CASES INVOLVING THE PROLIFT
AND PROLIFT +M PRODUCTS

RULE 26 EXPERT REPORT OF BOB SHULL, M.D.

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. The opinions which are held and expressed are as follows:

I. QUALIFICATIONS

I am Dr. Bob Shull. My Curriculum Vitae (attached as **Exhibit A**) reflects my training, background, and publications. I graduated from Tulane Medical School and completed my residency training in Obstetrics and Gynecology at the University of Virginia in Charlottesville.

Throughout my career, I have had an interest in pelvic floor disorders of women, including pelvic organ prolapse and stress urinary incontinence. I have published original work in scientific journals regarding the evaluation and surgical management of these disorders.

Currently, I am Professor in the Division of Gynecology and member of the Section of Female Pelvic Medicine and Reconstructive Pelvic Surgery at the Scott and White Memorial Clinic and Hospital, Texas A&M System Health Science Center College of Medicine, in Temple, Texas. In this role, I maintain an active patient practice, supervise and teach medical students, residents, and fellows, and participate in clinical and basic science research. I also teach and lecture throughout the United States and in other parts of the world, often leading "hands-on" surgical workshops for colleague physicians.

I have significant experience with pelvic repair surgery of all types. I have performed many pelvic surgeries for both incontinence and/or prolapse. I have lectured nationally and internationally regarding these surgeries, outcomes, and complications. I have personally examined, diagnosed and treated approximately one hundred patients with mesh complications and removed some mesh from at least 70 women. I am familiar with the Prolift and Prolift+M kits specifically, as well as mesh products generally. I have also published articles in peer-

reviewed journals relating to complications of synthetic mesh devices for prolapse repair, including Prolift.[1]

In formulating my opinions and preparing this report, I relied on my experience, the scientific literature, and corporate documents from the files of Ethicon, Inc. ("Ethicon"). The corporate documents were supplied to me by counsel.

II. SUMMARY OF OPINIONS

The following summarize my opinions in this case:

1. At the time of its introduction, there was insufficient scientific evidence supporting the implantation of the Prolift and Prolift+M devices for pelvic organ prolapse.

2. The Prolift and Prolift+M devices (and similar prolapse mesh "kits") represented a significant departure from traditional surgical procedures performed for pelvic organ prolapse.

3. The vagina is a different environment from the abdominal wall. Maintenance of vaginal compliance and distensibility is essential for bowel, bladder, and sexual function.

4. Insertion of a mesh device containing arms and involving the blind passage of trocars presents specific risks and is inconsistent with sound pelvic reconstructive surgical principles.

5. Traditional surgical repairs are effective. The medical literature does not show improved outcomes with the use of the Prolift or Prolift+M devices or any other transvaginally placed mesh.

6. Mesh is associated with severe, life-changing complications that are not seen with traditional pelvic reconstructive surgery and are often difficult to treat.

7. Mesh removal surgery is complex and requires special expertise. Removal may not alleviate the patient's symptoms and may, in fact, make the symptoms worse.

8. The characteristics of polypropylene mesh when implanted vaginally for pelvic organ prolapse including chronic inflammation, foreign body reaction, fibrosis and scarring, nerve entrapment, deformation, stiffening, shrinkage and contraction, and degradation have clinical significance.

[1] e.g. Huffaker, Shull, and Thomas, A serious complication following placement of posterior Prolift, Int Urogynecol J (2009) 20:1383–1385; Brubaker and Shull, A perfect storm, In t Urogynecol J (2012) 23:3-4

9. Ethicon did not provide doctors and patients with complete and accurate information regarding the complications associated with the Prolift and Prolift+M devices and their management.

10. Ethicon failed to disclose the lack of benefit of pelvic organ prolapse surgery using the Prolift and Prolift+M devices to physicians and patients.

11. There are no proper clinical trials demonstrating safety of the Prolift and Prolift+M devices before their introduction into the commercial market.

12. Ethicon should have anticipated the serious and permanent complications that are caused by the Prolift and Prolift+M mesh kits.

13. From a clinical perspective, Ethicon did not exercise due diligence in the design and development of the Prolift and Prolift+M devices.

14. Ethicon lacked scientific rigor in the testing and reporting of its pelvic floor products.

15. Ethicon did not heed the warnings from the hernia and gynecologic literature regarding the use of polypropylene mesh.

16. If Ethicon had properly tested its products, certain problems and complications would have been identified before they were used in a clinical setting.

17. Ethicon inappropriately marketed the Prolift and Prolift+M products to all physicians and did not properly train these physicians in the unique aspects of patient selection and patient counseling of long-term sequelae of trocar-based meshed kits.

18. After the products were used in general clinical setting, Ethicon did not systematically monitor their products or evaluate physician feedback.

19. The problems associated with Prolift and Prolift+M devices are inherent in the concept and design and occur even when the device is placed properly.

III. THE PROLIFT PROCEDURE (AND SIMILAR MESH "KITS") REPRESENTED A SIGNIFICANT DEPARTURE FROM SURGICAL PRACTICES AT THE TIME AND YET ETHICON DID NOT EXERCISE DILIGENCE IN THE DESIGN AND DEVELOPMENT OF THE PROLIFT AND PROLIFT+M DEVICES

The Ethicon Prolift and Prolift+M devices (and other polypropylene mesh "kits" designed for the treatment of pelvic organ prolapse) represented a radical departure from surgical practices at the time of their introduction. Implantation of the Ethicon Prolift, using trocars and

arms into spaces gynecologists were not familiar with created special risks.[2] These new "systems" were very different from mesh slings used to treat stress urinary incontinence.

The Prolift Pelvic Floor Repair System is a packaged kit complete with a uniquely shaped, pre-cut synthetic polypropylene mesh, Prolift trocars/guides, Prolift cannulas, Prolift retrieval devices, and a Prolift Surgical Guide and IFU. The Prolift Pelvic Floor Repair System come in three variations – the Prolift Anterior Pelvic Floor Repair System (for the treatment of cystocele), the Prolift Posterior Pelvic Floor Repair System (for the treatment of rectocele), and the Prolift Total Pelvic Floor System (for the treatment of cystocele, rectocele, and vaginal vault prolapse). Each Prolift kit includes mesh of identical composition and manufacturing as Gynemesh PS. Ethicon marketed Gynemesh PS for use in hernia surgery. The mesh is shaped and pre-cut for use in a specific compartment of the vagina.

The Prolift+M[3] Pelvic Floor Repair System is essentially identical to the Prolift system with the exception that the mesh grafts are composed of Ethicon's Gynemesh M mesh. Gynemesh M mesh has the same composition and construction as Ethicon's UltraPro, mesh constructed of a combination of absorbable (poliglecaprone or monocryl) and nonabsorbable (polypropylene) components. Ethicon marketed UltraPro for use in hernia surgery.

At the time the Prolift and Prolift+M devices were introduced, 2005 and 2008 respectively, there was insufficient scientific evidence that supported utilization of this specific system.[4] Case reports in the literature described problems with other, similar devices. Adverse events were occurring and being reported with all types of vaginal mesh for prolapse repair. There had been complications with some synthetic slings. Surgeons were discussing complications at scientific meetings. "Mesh complications" became a frequent topic at conferences. In fact, the little literature available plus a healthy degree of skepticism should have raised serious questions about the wisdom of the use of mesh kits used for vaginal surgery. The vagina is known to be a very different environment compared to the abdominal cavity and abdominal wall – areas where mesh had been placed previously.[5] Some of the unique features of the vagina include bacterial contamination,[6] dense innervation and vascularization (controlling sensation and function), close proximity to bowel and bladder, and the need for compliance and distensibility for bowel, bladder, and sexual function.

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[2] Prior to marketing the Prolift, an Ethicon marketing executive after watching a demonstration observed that the procedure to implant a Prolift would require a "major mind shift" for surgeons. ETH.MESH.02282833.

[3] UltraPro mesh was discussed internally as early as January 2005 (prior to the Prolift going on the market) as a potentially safer alternative mesh than Gynemesh PS which was used in the Prolift. UltraPro was thought to reduce scar contraction and lower the density of the scar formation. Neither animal studies nor trials were conducted to substantiate this claim before the launch of Prolift+M. *See* ETH.MESH.01760853- ETH.MESH.01760861.

[4] ETH.MESH.01160159, Gynemesh Prolene Soft mesh, pre-clinical functionality testing strategy, 11-1-2001, Conclusion: "Based upon the Gynemesh Prolene Soft mesh's product characteristics, intended clinical indications and the use of existing polymer materials, additional pre-clinical functionality testing is not required." *See* Giselle Bonet dep., 102:1-7 ("Q. At the time the Prolift was launched, the Prolift itself had not been studied in clinical studies, correct, meaning the actual packaged product with the preformed mesh and the instruments, that had not been studied clinically, correct? A. Correct.")

[5] ETH.MESH.00164607 ("The vagina is NOT the abdomen (nor similar to any other surgical environment").

[6] P1659; P1627.

Ethicon justified the development of mesh kits based on the presumption of high recurrence rates with traditional reconstructive procedures using native tissue repair.[7]

However, the underlying assumption of high reoperation rates is not supported by the literature. Using current definitions of "success," traditional surgery has been shown to be effective (with less than 10% reoperation rate) and is not significantly improved by the use of mesh, even in the anterior compartment. According to a recent review by Stanford, most studies show an anatomic success rate around 92% for native tissue repairs – identical to mesh repairs. (Stanford, 2012). When Chmielewski reanalyzed Weber's results from her 2001 study using contemporary, clinically relevant criteria for success, she found only 11% of subjects experiencing anatomic recurrence beyond the hymen, 5% of subjects experiencing symptomatic recurrence, and no subjects requiring surgery for recurrence or complications at 1 year. (Chmielewski, 2011).

Additional studies have confirmed the success of native tissue repairs. Oversand found that 94% of 699 women with native tissue repairs of pelvic organ prolapse expressed subjective satisfaction with low reoperation rates. (Oversand, 2013). Funk et al. examined the records of 27,809 anterior prolapse surgeries from insurance records. Of these, 24.7% included mesh. The 5-year cumulative risk of any repeat surgery was significantly higher for vaginal mesh versus native tissue (15.2 % vs 9.8 %) with a 5-year risk of mesh revision/removal of 5.9%. The 5-year risk of surgery for recurrent prolapse was similar between vaginal mesh and native tissue groups (10.4 % vs 9.3 %). (Funk, 2013). Gutman and Sokol have reported a randomized controlled trial with native tissue vs. mesh-augmented anterior repairs at one and three years. (Gutman and Sokol, 2013). The authors found no objective or subjective benefit, a mesh erosion rate of >15%, and a higher reoperation rate with mesh repairs. All reoperations for recurrence were in the mesh group. The authors concluded that the rate of surgery for recurrent prolapse was no different with or without mesh. The mean time to reoperation for recurrence reported in the literature is twelve years, lending little credence to efficacy results in short term studies. (Hagen, 2006).

There are no studies showing improved surgical outcomes using mesh in the posterior or apical compartments. Furthermore, there has never been a demonstration of better anatomic or functional results in the posterior or apical compartments.

Reoperation rates for all repairs are higher with mesh due to the need for surgical management of mesh complications. Current literature suggests that mesh procedures may also promote prolapse in compartments where mesh is not placed. Withagen et al. studied this issue,

[7] ETH.MESH.03904451. Ethicon's rationale for the introducing the Prolift was predicated on the failure rate. Howeer, initial Prolift advertising in 2006 claimed "less than 5% failure rate" at 3 months following implantation. Ethicon internal documents at that time, however, showed an approximately 20% failure rate – "Prof Jacquetin's data has not proved as positive as hoped – showing approx. 80% success rate – The data will be initially presented at IUGA in September. Note that this data is a retrospective study of over 100 patients using TVM technique, not necessarily used with Prolift. This less than 90% success rate forces us to differentiate Prolift from the TVM technique moving forward." ETH.MESH.00741137. Ethicon did not inform doctors that the failure rate at 12 months was 18.4%.

finding that "[t]ension-free vaginal mesh treatment of one vaginal compartment prolapse seems to provoke the development of vaginal prolapse in initially unaffected vaginal compartments." (Withagen et al., 2010). In my experience, surgeons are seeing apical (uterus, vaginal vault, or enterocele) prolapse through the scarred distal vagina resulting from mesh repairs. The apical compartment prolapse may be exaggerated after mesh placement because the other vaginal compartments are rigidly fixed in place.

The studies demonstrating good results with traditional prolapse repairs are consistent with my experience and give an accurate representation of success rates following native tissue prolapse repairs. A new surgical innovation, whether involving a device or not, should document equivalent efficacy; equal or superior intraoperative complication rates, post-operative recurrence rates, and re-operation rates before touting their product for widespread use. In addition, there should be a description of possible complications, how to avoid them and how to manage them.

IV. THE SERIOUS AND LIFE-CHANGING COMPLICATIONS CAUSED BY THE PROLIFT AND PROLIFT+M DEVICES WERE FORESEEABLE AND NOT DISCLOSED TO PHYSICIANS AND PATIENTS

A. The Serious and Life-Changing Complications Caused by the Prolift and Prolift+M Devices Were Foreseeable

Synthetic mesh implanted in the vagina using a kit such as the Prolift and Prolift+M products can cause life-altering and sometimes permanent injury and disability. These complications were foreseeable based on the medical and scientific literature, the known properties of polypropylene, experience with other similar devices, and adverse event reporting. By 2006, there was substantial evidence in the literature describing mesh complications with erosion at a significantly higher rate. Ethicon internal documents and studies indicate that postoperative vaginal erosion/extrusion occurred in 14.1% of cases. Over 50% of these exposures required surgical treatment.[8] The scientific literature bears this out this out as well. Female pelvic surgeons, especially those of us in academic positions and referral centers, are spending a great deal of time managing mesh complications and performing challenging and risky mesh explant or removal surgeries. Ethicon knew that the Prolift and Prolift+M devices were associated with a high rate of complications. Ethicon documents supporting this opinion can be found in Section VIII.a.

There is a great deal of scientific literature dealing with the material properties of polypropylene mesh and the host response. Reported mesh characteristics include chronic inflammation and foreign body reaction,[9] bacterial contamination,[10] shrinkage and contraction,[11]

[8] ETH.MESH.00081035; ETH.MESH.00081083; ETHC.MESH.00080954; ETH.MESH.00081006; ETH-01121-01122; ETH.MESH.00081000; ETH-01322.

[9] Elmer, C., B. Blomgren, C. Falconer, A. Zhang, and D. Altman. "Histological Inflammatory Response to Transvaginal Polypropylene Mesh for Pelvic Reconstructive Surgery." J Urol 181, no. 3 (Mar 2009): 1189-95; Smith, T. M., S. C. Smith, J. O. Delancey, D. E. Fenner, M. O. Schimpf, M. H. Roh, and D. M. Morgan. "Pathologic

Continued on following page

fibrosis and scarring,[12] embrittlement,[13] nerve involvement,[14] deformation,[15] and degradation.[16] Smaller pore, heavier weight meshes, like Gynemesh PS, are thought to intensify these reactions.

Studies also characterize the properties of Gynemesh, specifically. Some examples follow. In a study by Jones, Gynemesh was the stiffest of the meshes studied. Letouzey, et al., measured the shrinkage of Gynemesh with ultrasound over a nine year period in 40 patients.

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Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center." Female Pelvic Med Reconstr Surg 19, no. 4 (Jul-Aug 2013): 238-41; Iakovlev V., Carey ET, Steege J. "Pathology of Explanted Transvaginal Meshes." International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering 8, no. 9 (2014).

[10] Boulanger, L., M. Boukerrou, C. Rubod, P. Collinet, A. Fruchard, R. J. Courcol, and M. Cosson. "Bacteriological Analysis of Meshes Removed for Complications after Surgical Management of Urinary Incontinence or Pelvic Organ Prolapse." Int Urogynecol J Pelvic Floor Dysfunct 19, no. 6 (Jun 2008): 827-31; Vollebregt, A., Troelstra, A., & van der Vaart, C. H. . "Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: Are Additional Intraoperative Sterility Procedures Useful?". International Urogynecology Journal and Pelvic Floor Dysfunction 20, no. 11: 1345-51.

[11] Klinge, U., Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. "Shrinking of Polypropylene Mesh in Vivo: An Experimental Study in Dogs." The European Journal of Surgery 164, no. 12 (1998): 965-69; Velemir, L., J. Amblard, B. Jacquetin, and B. Fatton. "Urethral Erosion after Suburethral Synthetic Slings: Risk Factors, Diagnosis, and Functional Outcome after Surgical Management." Int Urogynecol J Pelvic Floor Dysfunct 19, no. 7 (Jul 2008): 999-1006; Tunn, R., A. Picot, J. Marschke, and A. Gauruder-Burmester. "Sonomorphological Evaluation of Polypropylene Mesh Implants after Vaginal Mesh Repair in Women with Cystocele or Rectocele." Ultrasound Obstet Gynecol 29, no. 4 (Apr 2007): 449-52; Feiner, B., and C. Maher. "Vaginal Mesh Contraction: Definition, Clinical Presentation, and Management." Obstet Gynecol 115, no. 2 Pt 1 (Feb 2010): 325-30; Jacquetin, B., and M. Cosson. "Complications of Vaginal Mesh: Our Experience." Int Urogynecol J Pelvic Floor Dysfunct 20, no. 8 (Aug 2009): 893-6.

[12] Klosterhalfen, B., K. Junge, and U. Klinge. "The Lightweight and Large Porous Mesh Concept for Hernia Repair." Expert Rev Med Devices 2, no. 1 (Jan 2005): 103-17; Cobb, W. S., K. W. Kercher, and B. T. Heniford. "The Argument for Lightweight Polypropylene Mesh in Hernia Repair." Surg Innov 12, no. 1 (Mar 2005): 63-9.

[13] Junge, K., U. Klinge, A. Prescher, P. Giboni, M. Niewiera, and V. Schumpelick. "Elasticity of the Anterior Abdominal Wall and Impact for Reparation of Incisional Hernias Using Mesh Implants." Hernia 5, no. 3 (Sep 2001): 113-8; Costello, C. R., S. L. Bachman, B. J. Ramshaw, and S. A. Grant. "Materials Characterization of Explanted Polypropylene Hernia Meshes." J Biomed Mater Res B Appl Biomater 83, no. 1 (Oct 2007): 44-9.

[14] Klosterhalfen, B., K. Junge, and U. Klinge. "The Lightweight and Large Porous Mesh Concept for Hernia Repair." Expert Rev Med Devices 2, no. 1 (Jan 2005): 103-17; Bendavid, R., Lou, W., Koch, A., Iakovlev, V. "Mesh-Related Sin Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain." International Journal of Clinical Medicine 5 (2014): 799-810; Iakovlev V., Mekel G., Blaivas J. "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh Is Not Inert [Abstract]." International Continence Society Meeting Annual Meeting (2014); Iakovlev V., Carey ET, Steege J. "Pathology of Explanted Transvaginal Meshes." International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering 8, no. 9 (2014).

[15] Margulies, R. U., C. Lewicky-Gaupp, D. E. Fenner, E. J. McGuire, J. Q. Clemens, and J. O. Delancey. "Complications Requiring Reoperation Following Vaginal Mesh Kit Procedures for Prolapse." Am J Obstet Gynecol 199, no. 6 (Dec 2008): 678 e1-4.

[16] Coda, A., R. Bendavid, F. Botto-Micca, M. Bossotti, and A. Bona. "Structural Alterations of Prosthetic Meshes in Humans." Hernia 7, no. 1 (Mar 2003): 29-34; Costello, C. R., S. L. Bachman, B. J. Ramshaw, and S. A. Grant. "Materials Characterization of Explanted Polypropylene Hernia Meshes." J Biomed Mater Res B Appl Biomater 83, no. 1 (Oct 2007): 44-9.; Iakovlev, V., Guelcher, S., Bendavid, R. "In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades." Virchows Arch Suppl 1 (2014): S35; Clave, A., H. Yahi, J. C. Hammou, S. Montanari, P. Gounon, and H. Clave. "Polypropylene as a Reinforcement in Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants." Int Urogynecol J 21, no. 3 (Mar 2010): 261-70.

They found a 10% per year shrinkage rate up to 85% at 8 years.[17] Liang (2013) found that Gynemesh caused more vaginal degeneration in primate implantation than other less stiff meshes. Feola (2013) found that Gynemesh resulted in deterioration of the biomechanical properties of the vagina – more so than less stiff meshes.

New studies document the increasing rates of severe complications associated with mesh, the difficulty treating these complications, the need for multiple surgeries, the failure of corrective surgery to alleviate the symptoms in many instances, and the life-changing disabilities women suffer. New onset chronic pain syndromes following mesh implantation are the most difficult conditions to manage. Sadly, many injured women are in worse condition after mesh implantation than they were prior to having the original surgery. These particular severe complications are not seen following traditional surgeries. (Hansen, 2014; Dunn, 2014; Abbott, 2014; Unger, 2014).

I watched videos of the implantation of the Prolift Anterior, Prolift Posterior, and Prolift Total. The video demonstrates how the arms of the mesh can become string-like and are no longer flat, as they are pulled through cannulas that have been threaded through the tissue.[18] Not only during implantation but after, the Prolift and Prolift+M arms are put under a considerable amount of strain, which may ultimately lead to mesh curling, roping, and deformation.[19] This issue of deformation of the Ethicon mesh is not explained in the Ethicon literature. Ethicon knew that the trocars, cannulas and mesh arms on the Prolift and Prolift+M products would cause tissue damage during implantation as well as after implantation due to the inflammatory response of the surrounding tissue to the mesh implant. Support for this opinion can be found in Section VIII.a.

When the mesh deforms, it becomes a cord-like, rigid, and taut instrument that can saw into the tissue, causing the pain that I see frequently in these patients. This issue was not addressed prior to the introduction of the Prolift devices and has turned out to have significant clinical implications. This phenomenon was reported by Feiner and Maher in their paper, Vaginal Mesh Contraction: Definition, Clinical Presentation, and Management, published in 2010. The authors concluded that vaginal mesh contraction is "a serious complication after prolapse repair with armed polypropylene mesh that is associated with substantial morbidity, frequently requiring surgical intervention." (Feiner and Maher, 2010).

Letouzy, et al. reviewed the long-term changes in pelvic mesh volumes over time using three-dimensional translabial ultrasonography and found mean contraction of 30%, 65%, 85% at follow-up durations of 3, 6, and 8 years, respectively. This study demonstrates that the

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[17] Letouzey V., et al. "Ultrasound evaluation of polypropylene mesh contraction at long term after vaginal surgery for cystocele repair." Int Urogyn J 2009;20(Suppl.2):S205-6.

[18] ETH.MESH.00419571-00419600 (Prolift Systems Surgical Technique guide).

[19] ETH.MESH.00034875, email 11-20-2008 from Jonathan Meek to Catherine Lepley and others: "Another point is that the tight-knit arms would result in a rope effect. Knowing that the tissue needs to grow through the arms as-well, this will be problematic in the patient. To be fair, it is an issue for everyone because if you 'yank' Gynemesh arms, they will also lose their porosity. The effect of roping is increased inflammatory response, increased risk of infection and denser scar plate (not much fun for the patient) …"; ETH-80647.; Kirkemo dep. (4-18), at p.135-138, p.150; Hinoul dep. (4-6), p.506-507.

pathological process that causes mesh shrinkage is progressive and there is linear evolution of the contraction rate with time, raising the concerning possibility that mesh contraction continues indefinitely.

At the IUGA Conference in 2009, the inventor of the transvaginal mesh technique used in the Prolift system, Professor Jacquetin, presented data indicating that painful mesh contraction occurred at a rate of 19.6%.[20]

From my review of Ethicon documents, I find no evidence that there was a systematic evaluation of the introduction of the actual cannulas, trocars, and retrieval devices in the female pelvis, grasping the arms of the mesh, and pulling the trocar and then the cannula back through multiple tissue layers in a highly vascularized and innervated area prior to the Prolift System being placed on the market. Ethicon apparently utilized the trocars and cannulas on cadavers.[21,22,23,24] However, cadavers are not a substitute for *in vitro*, *in vivo* studies or the mesh or careful investigation laboratory, animal and human trials. It is well known that cadaveric tissue does not maintain the same properties that are present in the tissue of a living human being. The main benefit of the cadaver model is to demonstrate gross anatomical landmarks, but a hemi-pelvis from a cadaver does not help the surgeon to understand individual anatomical variations. A cadaver cannot be used to evaluate the tissue response, nerve or blood vessel damage, anatomic or functional outcomes, safety concerns, or in vivo characteristics of the product. Support for these opinions can be found in Section VIII.a.

The serious complications associated with transvaginally placed mesh kits are now well-known to surgeons practicing in the area of female pelvic reconstructive surgery, and well-described in the medical literature. If Ethicon had performed the indicated testing before clinical marketing proceeded, including bench testing, animal studies, clinical trials, and examination of explanted meshes, these problems would have been identified.

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[20] L. Velemir, B. Fatton, B. Jacquetin: mesh shrinkage: How to asses, how to prevent, how to manage. IUGA Como, Italy, June 16-20, 2009.

[21] ETH.MESH . 02277482.

[22] The first Prolift Clinical Expert Report, dated November 10, 2004, reads as follows: "Cadaveric evaluations of prototype PROLIFT components have demonstrated that these devices and the system as a whole are suitable for use in performing pelvic floor repairs. These evaluations, in conjunction with all other elements required by Ethicon PR563-001, support release of a total of 30 kits to experienced D'Art clinical investigators in order to obtain an in-vivo assessment of system performance. This assessment is intended as an adjunct of Design Validation activities to confirm that evaluations made in cadaveric specimensreflect actual use." ETH-41142.

[23] 2-7-2005, ETH-01624, Prolift Design Validation, Comment: "Participant indicated that the ability for the cannula to facilitate user access to the retrieval device is poor." [Ethicon] response: "… during deep passages the tip of the cannula tended to get lost in deep tissues." In this context, "lost" means that the surgeon has to move the cannula around in the "deep tissue" of critical structures, including organs, arteries, veins, and nerves, while trying to retrieve the device. Damage caused by this maneuvering would not be evident in a cadaver.

[24] 2-7-2005, ETH-01626, Prolift Design Validation, Comment: "Entrance points were well defined but the exit points are not so clear." If the exit points of the cannula-equipped guides cannot be reproduced consistently, this increases the risk of damage to organs and major neurovascular structures in the pelvis and increases the risk of procedure failure if mesh is not secured correctly in the relevant supporting structures.

B. Ethicon knew about complications associated with their products and did not inform doctors as to how to manage them

I have reviewed the Ethicon Instructions for Use (IFU) and patient and doctor brochures for these products. Reviewing the information contained in these documents is something I do on a regular basis in my practice and in my capacity as an educator of medical students, residents, and colleague physicians. In my opinion, these documents do not provide adequate information for doctors and patients to make informed choices. They do not include the severity and frequency of the complications, a complete list of potential complications, the lack of clinical data to support their use, the difficulty in removing mesh, and the occurrence of permanent disability. The product literature also does not provide information regarding contraindications to the use of the product in women with fibromyalgia, painful bladder syndrome, or other chronic pain conditions. Ethicon documents supporting this opinion can be found in Section VIII.b.

The most obvious complication missing from the adverse reaction list is chronic pain. Severe and intractable pain following mesh prolapse repair is the most serious problem I see regularly in patients referred to me for the treatment of mesh complications. Ethicon knew that chronic pain could be a significant postoperative problem when these products are utilized in vaginal surgery, and yet it is not mentioned in Prolift 510(k) applications, labeling (IFU), or physician and patient education materials. Even though postoperative pain can occur with traditional prolapse surgery (vaginal prolapse repair with native tissue utilizing sutures or abdominal sacrocolpopexy), debilitating, life-altering pain following these procedures has rarely been a significant issue. When post-operative pain occurs, it is usually temporary, treatable, and typically does not result in long-term disability. Pain as a result of trocar placed, armed mesh kits is often life-altering and can be permanent. Ethicon was aware of this lack of viable treatment options, and should have investigated and recognized the complication of new onset and progressive pelvic pain and determined if effective treatment options were available or if this complication was preventable prior to marketing a permanently implanted medical device.

Ureter obstruction was identified by Ethicon in August 2007 as comprising 20% of post-operative complications over a 5-month period in 2007. It was raised as a serious issue because of the rapid progression into hydronephrosis and compromised renal function within a short period of time. Despite an indication of concern regarding the rate and potential severity of this complication, as well as acknowledgement that physicians did not seem certain how to address this complication when confirmed, the Prolift IFU implemented in December 2007 did not include any indication of urinary obstruction or retention, or ureteral obstruction in its warnings or adverse reaction listings. In 2005, voiding dysfunction was also identified as a post-operative problem which did not resolve for a year in some patients. It was not until 2009 that the Prolift IFU listed urinary retention/obstruction, ureteral obstruction, and voiding dysfunction as adverse reactions.

Another serious problem involves the removal of transvaginally placed mesh when complications do arise. Corrective surgeries for mesh complications are often lengthy, risky (due to the potential for further damage to nerves, bladder and bowel, and further scarring and retraction), invasive, and frequently do not completely resolve the problem. When urogynecolgists started seeing these severe complications, there were no established treatment

guidelines. Many specialists now have a significant portion of their practices occupied with handling mesh complications. Ethicon should have considered how to avoid or if unable to avoid how to manage the complications that they knew would occur and developed protocols for their management. Ethicon should also have communicated these protocols to the physicians they were training to implant their Prolift devices.

The Prolift IFUs stated throughout the time the product was on the market that: "The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is no absorbed, *nor it is subject to degradation* or weakening by the action of the tissue enzymes."[25] Ethicon failed to inform physicians and patients accurately and completely through the labeling and marketing materials. This information would have been important to physicians in evaluating the risks and benefits of the Prolift device which was intended to be a permanent implant for the life of the patient. This information would also have been important for physicians to know in order that they might have a complete informed consent discussion with their patients.

In its own materials, Ethicon described the Prolift Pelvic Floor Repair System as utilizing a "revolutionary" surgical technique. Ethicon should have considered how to avoid, recognize, and manage the complications that they knew would occur and developed protocols for their management. Ethicon should also have addressed these complications and communicated the protocols to the physicians they were training to implant their Prolift devices.[26, 27] Ethicon received requests from physicians regarding such additional instruction, but no company documents were found supporting a change in training protocols.[28] The blind insertion of the trocars through the obturator foramen, ischiorectal fossa, ileococcygeus muscle and sacrospinous ligament is a drastic departure from traditional non-mesh surgery, which is performed under direct vision. Ethicon was aware of the degree of discomfort physicians had with the procedure from feedback during training courses, as well as the high percentage of surgeons who needed to be retrained.[29,30] This percentage was surprisingly high, considering Ethicon was initially very selective as to the skill level those attending training sessions.[31]

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[25] ETH.MESH .02341526 (emphasis added). The IFU maintained this claim throughout the time the Prolift was on the market.

[26] ETH.MESH.00847816 (Comment from Dr. Butrick to Ethicon Medical Director, David Robinson: "I sure am tired of seeing these pts with bad myofascial pain after Prolifts. The doctors need to be taught how to identify pf pain disorders and avoid placing meshes thru these spastic muscles.")

[27] ETH.MESH.02289896 (slide from Dr. Butrick, "The aggressive surgery flares the pre-existing myofascial pain…"

[28] ETH.MESH.01184009 (2009 Surgeon Summit Breakout Session – February 7 Survey Results: "The improvements requested for PROLIFT are mostly around training; this is felt to be a big need. There is not sufficient education regarding peri-obturator anatomy and there is a failure of surgeons to understand the anterior apical passage."

[29] ETH.MESH.02282833 ("The consensus is that some doctors will need more than one exposure to TVM surgery before they feel confident to be able to start the procedure (even those with high skill sets)."

[30] ETH.MESH.00031359 "16 of the 84 have needed to be re-trained (19%)…"

[31] ETH-83128

Other well-known complications Ethicon failed to cite in their warnings include nerve damage (sometimes permanent), vaginal scarring,[32] de novo stress urinary incontinence, other bladder and bowel dysfunction, impairment of sexual function, foreign body reaction to synthetic products, chronic infection, recurrence of prolapse, and partner discomfort or injury with sexual intercourse.

At the time the Prolift was marketed and sold, Ethicon was aware of issues with erosion, infection, scarification, and the significant problems these issues could create.[33] However, I could not find any Ethicon documents advising surgeons how to treat these complications. The warning label should have stated that polypropylene lasts a lifetime and complications may require additional surgeries that may or may not correct the newly acquired problems. Doctors should have been told that these complications were serious and could be life altering for their patients.

C. Ethicon did not inform doctors as to which patients were poor candidates for the Prolift procedure

The IFUs for the Prolift Products include the following contraindication: "When GYNECARE GYNEMESH PS mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows."[34] There is nothing to document specifically who would most likely benefit from the product use. Patient selection is important. Ethicon should have determined and informed doctors what subpopulations of women were appropriate candidates for their products or more importantly, who is not a satisfactory candidate.

When a device or operation does not have a proven track record, this information can only be obtained through clinical trials. One example is the use of these prolapse mesh kits in women who have a pre-existing history of chronic pelvic pain. It is my opinion that mesh products should not be used in women with a history of chronic pelvic pain.

Another example where extreme caution should have been used is in women who are sexually active. It is my opinion that the risk of dyspareunia is unacceptably high following the placement of a prolapse mesh kits and that they should not be used in women who are sexually active unless the patient is extensively counseled on the possibility that her sexual function will be significantly and permanently impaired.

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[32] ETH.MESH.03021946 ("Pelvic Floor materials are still over-engineered . . . we need less foreign body material . . we need: Materials that correlate to measured female pelvic physiological characteristics."

[33] P.1659.

[34] ETH.MESH.02341522; ETH.MESH.02341454. In 2009, Ethicon added contraindications: "GYNECARE GYNEMESH'" PS Mesh must always be separated from the abdominal cavity by peritoneum. GYNECARE GYNEMESH'" PS Mesh must not be used following planned intra-operative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which may lead to infection that may require removal of the mesh. The GYNECARE PROLIFT' System should not be used In the presence of active or latent infections or cancers of the vagina, cervix, or uterus." ETH.MESH.02341734.

Studies after commercialization of the Prolift suggest that patients who have diabetes and women who smoke have a much great risk of erosion. Ethicon should have provided this information to physicians so that they could properly counsel their patients.

D. Ethicon formed a special interest group with other mesh manufacturers to further market its prolapse mesh kits

Ethicon (along with American Medical Systems, Bard, and Boston Scientific Corporation) gathered a group of mesh proponents to form the Pelvic Health Coalition to influence reimbursement. Publicly, the PHC claimed to be "committed to raising awareness of pelvic prolapse by promoting and expanding patient, public, and professional education; promoting advocacy efforts; and strengthening the voice of the pelvic prolapse community" However, internal documents reveal that the organization had one primary mission – "the purpose being to improve hospital reimbursement for pelvic floor procedures which utilize synthetic or autologous products".[35]

The PHC petitioned the Centers for Medicare and Medicaid Services to create additional codes and "add-in" codes for mesh grafts for prolapse repair procedures. The PHC claimed that these codes would allow for "better data collection, outcomes research, and enhance the - quality of women's health care."[36] Ethicon rationalized the increased reimbursement based on shorter operating times (not proven), lower reoperation rates (not proven). Ethicon, under the guise of the PHC also attempted to postpone the FDA's public health notification[37] and claimed credit for the change in language of the ACOG Practice Bulletin #79.[38]

V. THERE ARE SAFER ALTERNATIVES TO THE USE OF THE PROLIFT AND PROLIFT+M POP MESH KITS THAT ARE EFFECTIVE AND HAVE VIRTUALLY NONE OF THE DEVASTATING COMPLICATIONS SEEN WITH THESE PRODUCTS

There are safer alternatives to the Prolift mesh devices. As discussed previously, the whole premise of transvaginal mesh kits was based on the inaccurate perception of high recurrence rates when traditional reconstructive procedures using native tissue repair were performed. However, the underlying assumption of high rates of recurrence is not supported by the literature. Devastating complications could have been predicted and did, in fact, occur. These severe complications had virtually never been reported with traditional native tissue repairs. Unlike mesh repairs including the Prolift procedure, the complications of native tissue repairs are known and the treatments are well-established.

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[35] ETH.MESH.00136420, ETH.MESH.00738769, ETH.MESH.01280816, ETH.MESH.01280860, ETH.MESH.00720002.
[36] ETH.MESH.00720002.
[37] ETH.MESH.02312098.
[38] ETH.MESH.02316434.

For surgical treatment of cystocele, an anterior colporrhaphy or site-specific native tissue repair using suture is quite effective with success rates of about 90%. Complications are infrequent, treatable, and related to the surgery itself and the immediate post-operative period. Of course, mesh erosion does not occur. Other complications, such as chronic pain or debilitating dyspareunia are uncommon.

A rectocele is traditionally treated with posterior colporrhaphy, a procedure to plicate the subepithelial vaginal connective tissue. Painful intercourse can occur following a posterior repair, but is uncommon as a long-term problem.

Surgical options for women with vaginal apical prolapse include transvaginal suspension procedures using native tissue and sutures, such as sacrospinous ligament fixation and uteroscaral ligament suspension or sacral colpopexy, which can be performed abdominally, laparoscopically, or robotically. Although sacral colpopexy uses synthetic mesh, it does not have the same risks of new onset pelvic pain or the same likelihood of erosion as mesh placed vaginally.

In 2000, I published our experience at Scott and White with apical prolapse treated with transvaginal reconstructive surgery with native tissue. In this series of 302 patients, 87% had optimal anatomic outcomes, with no persistent or recurrent support defects at any site. Thirteen percent had one or more sites with at least grade 1 loss of support, but the majority of these were grade I defects detectable only on careful pelvic exam. Morbidity included a 1% transfusion rate, a 1% ureteral injury or ureteral kinking rate, and a 0.3% postoperative death rate (an 85 year old woman with dementia died at home 4 days after the surgery with no autopsy). None of the ureteral injuries resulted in permanent disability. (15). We also reported on the recognition and management of nerve entrapment pain after uterosacral ligament suspension. Eight (1.6%) of 515 patients had neuropathic pain postoperatively that was treated immediately by removing the sutures on the affected side. In all patients, the pain resolved. (16). This situation is very different from the nerve injuries and complex neuropathic pain conditions that I see with mesh. With mesh-related neuromuscular pain, the location is variable, the pain can present immediately or remotely, and the new onset pain can be very difficult to treat, often requiring more than one operation and with less than optimal success.

Paraiso et al. (1996) reported on 243 patients (mean follow-up 73.6 months) who underwent sacrospinous ligament suspension and pelvic reconstruction. Recurrence of prolapse occurred over time, but only 4.5% underwent subsequent pelvic reconstruction. Defect-free survival rates at 1, 5, and 10 years were 88.3%, 79,7, and 51.9%, respectively. I had the opportunity to review this manuscript and write the Comment. I noted the importance of the following principles needed for successful reconstructive surgery: 1) correction of all anatomic defects; 2) maintenance or restoration of normal bowel and bladder function; and 3) maintenance of the vaginal canal for sexual function. Attempting to use a standardized operation with mesh kits when an individualized approach is required invites problems after surgery. Operations for prolapse require diagnostic acumen and technical execution of a procedure that is tailored to the individual patient's anatomy, symptoms, and desires.

I reviewed the full-length articles available for the Prolift and Prolift+M Systems. I have not summarized each of them but below present my observations regarding a sample of the major studies. The published literature does not support a conclusion that the benefits of surgical repair with the Prolift or Prolift+M Systems exceed the risks. The failure rate is shown to be comparable or worse than traditional repairs. The risk of complications such as mesh exposure, mesh shrinkage/contraction, pain, dyspareunia and voiding dysfunction is unacceptably high.

A. Prolift

1. Jacquetin (2010)

This study by some of the inventors of the Prolift presented 3-year follow-up on 85 of the 90 women (94%) enrolled in the French TVM study. Of the 90 women enrolled, 14 women (16.3%) had stage II prolapse with the remaining women having stage III prolapse. The authors reported failure (recurrent prolapse > stage I) in 15 of 86 women (17.4%) at 1-year follow-up, including 1 woman with reoperation for recurrent prolapse. The authors then reported failure in 17 of 85 women (20%) at 3-year follow-up, including 3 women with reoperation for recurrent prolapse. The authors reported in this article that 12 of 90 patients (13.3%) required reoperation, 3 for recurrent prolapse, 8 for mesh exposure, and 1 with vesicovaginal fistula. Within the text of the article, 4 other patients (for a total of 16 of 90, 17.8%) were described who required reoperation, including 1 patient each with urinary retention requiring mesh release, evacuation of hematoma, hematoma leading to mesh extrusion requiring mesh resection, and mesh retraction requiring resection. Furthermore, these data did not include 14 additional patients (for a total of 30 of 90, 33.3%) who required reoperation within the first year of follow-up, including 9 patients treated with TVT-O for new stress incontinence, 1 patient with section of TVT-O for voiding impairment, 1 patient with section of vaginal adhesions, and 3 patients requiring other operations. Therefore, the authors underreported the frequency of reoperation by a factor of 2.5 times. At 1-year, moderate or severe vaginal stiffness (loss of elasticity) could be detected by digital exam in 12.6% of patients (11 of 90). No new cases were reported at the 3-year follow-up exam. Of the 61 patients who were sexually active at baseline, only 36 (59%) remained so at 3 years. The authors conclude that "Medium-term results demonstrate that the TVM technique provides a durable prolapse repair." However, the results make clear that the risks outweigh the benefits in light of the 20% failure rate, reoperation rate of 33.3%, and the fact 41% of women suffered loss of sexual activity.

2. Velemir (2011)

This study by the French TVM group assessed 91 women at least 1 year after the Prolift procedure, which included 75 anterior and 62 posterior Prolift mesh implants. Mesh retraction was estimated by palpation relative to the original length of the mesh and was defined qualitatively as absent, moderate (< 50%), or severe (≥ 50%). In addition, ultrasonography was performed to measure mesh length and thickness. Anterior mesh retraction was moderate in 80% and severe in 9.3% of patients. Posterior mesh retraction was moderate in 48.4% and severe in 9.7% of patients. With both anterior and posterior Prolift mesh implants, mesh retraction was strongly associated with increased mesh thickness and higher frequency of recurrent prolapse. In the 7 patients with severe anterior mesh retraction, maximum mesh thickness was 4.1 ± 0.9 mm,

and 5 of the 7 patients (71%) had recurrent anterior vaginal prolapse. In the 6 patients with severe posterior mesh retraction, maximum mesh thickness was 4.6 ± 1.3 mm, and 3 of the 6 patients (50%) had recurrent posterior vaginal prolapse. The authors described and depicted that severe mesh retraction resulted in lack of mesh covering the distal (closer to the vaginal opening) bladder and rectum, leading to recurrent prolapse. The authors felt this explained why the frequency of recurrent prolapse increased between 3 months and at least 1 year after the Prolift procedure, due to ongoing mesh retraction caused by the chronic inflammatory and foreign body reaction. The authors also stated that mesh retraction was probably a factor contributing to postoperative pain and dyspareunia, although clinical correlation with pain was not reported in this study. Ethicon marketed the Prolift procedure as "new" and "revolutionary" without the least understanding of how the Prolift mesh implant would behave in the vaginal environment. Ethicon knew that mesh retraction caused serious clinical consequences in hernia repair, and Ethicon had to know that those serious clinical consequences would occur at the same level, if not worse, in vaginal prolapse repair. From the first reports of the TVM technique using Gynemesh PS mesh, mesh retraction was known to be a frequent and serious complication, yet it was not included in the Prolift IFU. Ethicon failed to warn surgeons and patients of the severe clinical consequences and lack of effective prevention or treatment of mesh retraction.

3. Miller (2011)

This study, authored by Ethicon consultants and an Ethicon employee, reported the 5-year results for 66 of 85 patients (78%) originally enrolled in the US TVM study. A total of 15 of 66 patients (22.7%) met criteria for failure in the treated compartment, including 10 patients with ≥ stage II prolapse and 5 patients requiring reoperation for recurrent prolapse. Overall failure occurred in 33.3% (90% CI, 23.8-44.1%). Although the authors claimed that these results demonstrate stability of the anatomic outcomes, in fact, the TVM failure rate nearly tripled from 1 year (12%) to 5 years (33.3%).

The authors reported data inaccurately to underrepresent the true frequency of complications by using the total study population of 85 women as the denominator in reporting the frequency of complications, rather than the appropriate denominator of 66 women who attended 5-year follow-up. For example, mesh exposure was reported as 19% (16 of 85 patients), rather than the true frequency at 5 years of 24% (16 of 66 patients). Voiding dysfunction was misreported as 9% (8 of 85 patients), rather than the true frequency at 5 years of 12% (8 of 66 patients). The original Prolift IFU had no warning regarding voiding dysfunction, and the revised Prolift IFU revised only stated that normal voiding could be impaired "for a variable length of time," and did not indicate that voiding dysfunction could be prolonged, if not permanent.

Although the authors claimed that the most important finding of their study was "… the lack of new morbidity after the early (1 year) postoperative period," it would be more accurate to state that the same type of morbidity occurred again and again over the 5-year period. As reported in this article, a total of 29 of 66 women (44%) required reoperation, including 13 for stress incontinence, at least 9 for mesh exposure, 5 for recurrent prolapse, and 2 for fistulas, although the authors did not state this finding directly. The frequency of reoperation for complications was exceedingly high and vastly higher than anything reported with traditional vaginal prolapse surgery or even abdominal prolapse surgery.

Consistent with the 3-year results of the French TVM study, nearly one-third of preoperatively sexually active women abandoned sexual activity after the Prolift procedure, which strongly suggests that the TVM procedure impaired sexual activity in ways that were not assessed. However, the authors did not present the data in such a way that it was obvious that nearly one-third of the women (13 of 40, 32.5%) stopped being sexually active, and they did not discuss this in the article. Instead, by stating that only 1 woman developed new dyspareunia after the TVM procedure, the authors had the audacity to claim that their results "seem to confirm a net positive effect on sexual activity following prolapse surgery despite the use of mesh."

The authors concluded that "Five-year results indicated that TVM provided a stable anatomic repair." This is not true. However, as with the conclusions drawn from the 3-year results of the French TVM study, they provide no summary statement to indicate the human cost of achieving this so-called "stable anatomic prolapse repair," including reoperation in nearly half of the patients and loss of sexual activity in one-third of the patients. Indeed, the reoperation rate after the TVM procedure increased markedly over time, from 23-25.3% at 1 year, 33.3% at 3 years, and at least 44% at 5 years. Given the life-long risk of mesh-related complications and the deterioration of "benefit" as prolapse recurs over time, the risks of the TVM procedure greatly outweigh the benefits.

4. DeLandsheere (2012)

This study reported the results of a retrospective study after the index procedure was performed between January 2005 and January 2009, with follow-up of a median of 38 months (range, 15-63 months) in 524 women after Prolift procedures, including 48 women (9%) after anterior Prolift, 103 women (20%) after posterior Prolift, and 373 women (71%) after total Prolift procedures. In 286 women, anterior and posterior Prolift procedures were performed with uterine conservation. Of a total of 600 women in the consecutive series, 68 women were lost to follow-up, and 8 women died (including 1 woman who died of endometrial cancer 3 years after Prolift with uterine conservation). Of the 76 women not included in the primary analyses, 7 women (9.2%) had post-Prolift surgery. In the study population, 98 of 524 women (18.7%) had previous surgery for prolapse; therefore, the majority of women were having primary repair of prolapse.

Overall, 76 of 524 patients (14.5%) required reoperation after the Prolift procedure (see Table 2), although the article reported that only 61 of 524 patients (11.6%) required reoperation. A total of 19 women had reoperation for mesh complications, including 13 women with mesh exposure (within a median of 13 months from the index Prolift procedure), 1 woman with infected mesh (who subsequently developed recurrent prolapse after complete mesh excision), 2 women with mesh retraction, 2 women with rectal compression, and 2 women with vaginal synechia. One of these women had both mesh retraction and mesh exposure. In addition, 16 women had reoperation for recurrent prolapse within a median of 23 months from the index Prolift procedure. Although this article reports a lower frequency of reoperation than other articles, it must be emphasized that this represents the work of the TVM group that has the longest experience in performing transvaginal mesh prolapse surgery. Unfortunately, the other reports in the literature (including some of the early reports from the TVM group itself) demonstrate that these favorable results were not consistently reproduced in other studies.

5. The Iglesia Series (Iglesia (2010) & Sokol (2012)

Iglesia, et al. published 2 articles on the same study population with varying lengths of follow-up. The first article reported minimum 3-month follow-up and median follow-up of 9.7 months (range, .24-26.7 months); and the second reported minimum 1-year follow-up and mean follow-up of 14.7 months. The original study population consisted of 65 women with multi-compartment prolapse, 33 randomly assigned to the vaginal surgery group (most commonly treated with uterosacral ligament suspension, anterior and/or posterior colporrhaphy) and 32 women to the Prolift group (treated with anterior, posterior, or total Prolift). The data safety and monitoring board halted enrollment in the study when the mesh erosion rate surpassed the predetermined stopping criteria. Previous surgery for prolapse had been performed in only 4 of 65 women (6%); baseline prolapse was stage II in 11 of 65 patients (17%).

Recurrent prolapse as an anatomic outcome was defined as ≥ ICS POPQ stage II. By the definition of anatomic outcome, recurrent prolapse was no different in the non-mesh group compared to the Prolift group. In the non-mesh group, recurrent prolapse occurred in 70.4% at early follow-up and 69.7% at later follow-up. In the Prolift group, recurrent prolapse occurred in 59.4% at early follow-up and 62.5% at later follow-up. However, no patients in the non-mesh group required reoperation for prolapse, and 3 of 32 patients (9%) in the Prolift group had reoperation for recurrent prolapse. At each point of follow-up, no difference in symptom resolution existed between the 2 groups. The study assessed quality of life and symptoms using validated questionnaires and found no difference between the 2 groups. There was no difference in the proportion of patients with subjective cure of vaginal bulge symptoms between the non-mesh group (90%) and the Prolift group (96.2%).

Complications occurred more commonly in the Prolift group, including mesh exposure in 5 patients (15.6%). At later follow-up, 5 patients in the Prolift group required 6 operations, compared with none in the non-mesh group. Ethicon did not update the Prolift IFU to adequately inform physicians about the expected frequency of Prolift mesh erosion,

6. Altman (2011)

Altman, et al. published a randomized clinical trial comparing anterior colporrhaphy in 189 patients to the anterior Prolift procedure in 200 patients with 1-year follow-up. The primary outcome was defined as a composite of prolapse at ICS stage 0 or I and no symptoms of vaginal bulging. At 1 year, 60.8% of the Prolift group met the criteria for success, compared with 34.5% of the anterior colporrhaphy group. The Prolift group also had better results when the primary outcome was evaluated separately by its 2 components, prolapse stage and symptom of vaginal bulging. For prolapse at ICS stage 0 or I, 82.3% of the Prolift group versus 47.5% of the anterior colporrhaphy group met this criterion. For no symptom of vaginal bulging, 75.4% of the Prolift group versus 62.1% of the anterior colporrhaphy group met this criterion.

The Prolift group experienced more intraoperative and postoperative complications, including a higher frequency of reoperation after only 1 year. Reoperation was necessary in 13 patients (6.5%) in the Prolift group versus 1 patient (0.5%) in the anterior colporrhaphy group.

Average operative time was almost twice as long in the Prolift group (52.6 minutes) compared to the anterior colporrhaphy group (33.5 minutes). New stress incontinence was twice as likely in the Prolift group (12.3%) as in the anterior colporrhaphy group (6.2%). Pain with sexual intercourse was almost 4 times higher in the Prolift group (7.3%) compared to the anterior colporrhaphy group (2%). Pain was experienced more frequently in the Prolift group (inguinal pain in hospital, 2.5%; severe pelvic pain at 2 months, 2.5%; and severe pelvic pain at 1 year in 0.5%) versus in the anterior colporrhaphy group (no inguinal pain in hospital, severe pelvic pain at 2 months, 0.5%; and no severe pelvic pain at 1 year).

The majority (84%) of patients in the study population were undergoing primary repair of prolapse. About half (52%) had an early stage of prolapse (stage II, within 1 cm of the hymen); indeed, only 84% of patients experienced the symptom of vaginal bulging before surgery. ACOG/AUGS and the SGS do not recommend surgical intervention in patients who are at an early stage of prolapse and have some experienced symptoms of vaginal bulging and discomfort.

The authors cautioned that "Patients should understand, however, that the use of mesh may cause complications even after the immediate postoperative period." The authors concluded that "When one is counseling patients regarding surgical options, the benefits of the mesh kit must be balanced against the higher rates of surgical complications and postoperative adverse events associated with this approach." Because Ethicon failed to provided adequate information regarding the true risks of pain, contracture, chronic inflammation, and other adverse events to physicians through the Prolift System IFU and other materials, physicians would not have had sufficient information to properly counsel patients prior to implantation.

7. The Withagen Series

The Withagen group published 2 articles on the same study population, one with the primary 1-year outcomes of the RCT and a secondary analysis of new prolapse in the untreated compartment. In addition, a prospective cohort study reported predictors of failure after Prolift procedures. The study population was restricted to women with recurrent prolapse, although almost half (47%) had only stage II prolapse. Patients were randomly assigned to conventional prolapse repair (n=97) or Prolift procedures (n=93). Conventional prolapse repair included anterior and/or posterior colporrhaphy and sacrospinous or uterosacral ligament suspension. The Prolift procedures included anterior, posterior, or total procedures; 7 patients in the Prolift group also underwent conventional apical repair.

At 1 year, failure (defined as ≥ stage II prolapse) occurred in 38 of 84 (45%) of the non-mesh group and in 8 of 83 (9.6%) of the Prolift group. In contrast to the anatomic outcomes, subjective improvement occurred in equal proportions in both groups, 64 of 80 (80%) in the non-mesh group and 63 of 78 (81%) in the Prolift group. Both groups experienced a similar decrease in symptoms and improvement of quality of life measured by the Urogenital Distress Inventory (UDI).

Intraoperative and postoperative complications were more frequent in the Prolift group versus the non-mesh group, including bladder injury in 2 versus 0 patients, hematoma in 6 versus 1 patients, and temporary urinary retention in 16 versus 5 patients. Levels of new-onset pain,

dyspareunia, and stress incontinence were similar in both groups. In the Prolift group, 14 of 83 women (16.9%) developed mesh exposure, and 5 women required surgical treatment; 7 women had persistent mesh exposure at 1-year follow-up. In the Discussion, the authors expressed concern about the unknown effects of long-term presence of nonabsorbable mesh in the vagina and, because of this concern, suggested that Prolift be reserved for patients with recurrent prolapse.

The second article (Withagen BJOG 2012) reported a much higher frequency of new prolapse in untreated compartments in the Prolift group. At 1 year after surgery, 10 of 59 women (17%) in the non-mesh group versus 29 of 62 women (47%) in the Prolift group were diagnosed with new prolapse stage II or higher in the untreated compartment. In the Prolift group, women with new prolapse were significantly bothered as reflected in a higher score (13.1 ± 24.2) in the prolapse domain of the UDI, compared to women without new prolapse (2.9 ± 13.9). Of interest, when additional apical support was performed with anterior Prolift, the development of new prolapse was significantly reduced, underscoring the inadequacy of the anterior Prolift procedure to provide sufficient apical support.

The third article (Milani 2012) reported on 433 patients with 1-year follow-up after Prolift procedures. Failure (defined as recurrent prolapse ≥ stage II) in the treated compartment occurred in 15%. Overall failure in any compartment occurred in 41%. Failure defined as prolapse beyond the hymen and the presence of vaginal bulge symptoms or repeat surgery occurred in 9%. A consistent predictor of failure for all definitions was the combined anterior/posterior Prolift procedure with uterine conservation.

8. Maher (2011)

This article reported 2-year outcomes after laparoscopic sacral colpopexy (n=53) versus total Prolift (n=55) for women with posthysterectomy vaginal vault prolapse. Although preoperative prolapse stage was not provided, entry criterion required that women had at least stage II vaginal vault prolapse, and average baseline POPQ point C was 2.6-2.8 cm beyond the hymen, indicating advanced prolapse. Objective success, defined as < stage II prolapse at all sites, was more frequent after laparoscopic sacral colpopexy, 41 of 53 (77%), than after Prolift, 23 of 55 (43%). Symptomatic prolapse occurred in 1 woman after laparoscopic sacral colpopexy and 4 women after Prolift. Although both groups experienced similar improvements in quality of life, satisfaction was higher in the laparoscopic sacral colpopexy group (87 ± 21) than in the Prolift group (79 ± 20). The authors attributed this difference in patient satisfaction to the much higher reoperation rate in the Prolift group. In the laparoscopic sacral colpopexy group, 3 women (5.7%) had surgery (1 each for TVT, trocar hernia, and mesh erosion), and in the Prolift group, 12 women (22%) had 15 reoperations (4 for mesh contracture, 3 for suburethral tapes, 3 for recurrent prolapse, and 2 for mesh erosion). Vaginal mesh erosion occurred in 1 patient in the laparoscopic sacral colpopexy group and 7 patients in the Prolift group.

This is the only RCT comparing the Prolift with a laparoscopic sacral colpopexy. Although the laparoscopic sacral colpopexy group had longer operating time compared with the Prolift group (median 97 minutes versus 50 minutes), intraoperative blood loss was less (median

100 mL versus 150 mL), hospital stay was shorter (median 2 days versus 3 days), and patients returned to normal activity an average of 5 days sooner.

9. Frankman (2013)

This study was done to determine frequency, rate, and risk factors associated with mesh exposure in women who underwent Prolift repair. The retrospective chart review was performed for 201 women who were implanted between September 2005 and September 2008. Mesh exposure occurred in 12% (24/201), and the frequency was found to be higher when mesh was placed in the anterior compartment versus the posterior (8.7% vs. 2.9%, P=0.04). Of additional interest, the authors observed a 7-fold increased risk of mesh exposure in women with diabetes.

10. McDermott (2013)

The aim of this study was the comparison of postoperative anatomical outcomes following sacral colpopexy (SC) with outcomes following transvaginal mesh colpopexy (TVMC) with total Prolift in obese women. Fifty-six women underwent SC and 35 underwent TVMC, with a follow-up between 6 and 12 months. Follow up ranged from 6 to 12 months. SC patients showed significantly higher anterior and apical POP-Q measurements ($p<0.05$), as well as showing significant difference in overall POP-Q stage, with more recurrences in the TVMC group (32% vs. 12% in the SC group; P=0.03). The odds ratio indicated those in the obese TVMC group were 4.4 times more likely to have a stage II recurrence than those in the obese SC group.

11. Rogowski (2013)

A study done by Rogowski, et al., aimed to determine correlations between mesh retraction after anterior vaginal mesh repair and vaginal pain, de novo SUI, and overactive bladder. Subjects consisted of 103 women with stage 3 and 4 symptomatic prolapse of the anterior vaginal wall that underwent Prolift anterior implantation. Patients were interviewed at a 6-month follow-up, and underwent a cough stress test, and an introital/transvaginal ultrasound to measure the mesh length. The overall reduction in mesh length was found to be about 50% at 6-month follow-up. Mesh retraction was significantly larger (5.3 cm vs. 4.2 cm; $p<0.01$) in a subgroup of patients who reported postoperative vaginal pain (n=23; 22.3%) as compared with those that did not report pain. Additionally, a significant correlation was found ($R=0.4$, $p=0.01$) between mesh retraction and the severity of vaginal pain. Also, the percentage of patients with postoperative vaginal pain was significantly higher in the high mesh retraction group (35%) than in the low mesh retraction group (10%; $p<0.05$). Retraction was larger (5.0 cm vs. 4.3 cm; $p<0.05$) in a subgroup of patients that presented de novo OAB symptoms (n=20; 19.4%) as compared to those that did not. The percentage of these patients with de novo OAB was significantly higher in the high mesh retraction group (27%) than in the low mesh retraction group (12%; $p<0.05$). This study shows that patients with a larger amount of retraction were significantly more likely to present with both de novo OAB symptoms and de novo vaginal pain.

The authors suggest that local inflammation, neurogenic factors (e.g., nerve trapping), and /or displacement of the bladder neck may be contributory factors.

12. Khan (2014)

In order to evaluate the anatomical, functional and post-operative outcomes of Prolift, 106 subjects with either grade 2 prolapse or higher or recurrent prolapse, underwent Prolift mesh repair with anterior, posterior or total Prolift. Three (2.8%) of patients were re-operated due to recurrent prolapse in the operated compartment, and 14 (13.2%) underwent another operation due to prolapse in the non-operated compartment. At a median of 4 years, the patients were contacted and 82 agreed to a clinical review, while 19 chose a telephonic follow-up. Of the 82, 6 (7.3%) had developed a recurrence of prolapse in the operated compartment, while 16 (19.5%) had developed a prolapse in the non-operated compartment, with a total recurrence rate at 4 years of 26.8%. Upon vaginal exam, 13 (15.8%) were tender, and 3 (3.6%) had asymptomatic mesh exposure. Mesh exposure over the entire study period was noted in 6 (5.6%) women, and partial mesh excision was performed in 5. De novo SUI was found at a rate of 5.6%. Thirty-four of the 82 women were still sexually active, and 9 (26.4%) of these complained of some degree of dyspareunia. Authors considered their success rate to be 89.9%, as they did not count prolapse in another compartment as a failure because that compartment had not been treated by a Prolift mesh.

13. Kozal (2014)

Midterm morbitity and functional outcomes were assessed retrospectively with a mean follow-up of 9.5 months in 112 patients who underwent the Prolift procedure (anterior, posterior, and total). The median follow-up was 49.5 months (range: 16-85). A total of 25 subjects (22%) had postoperative and late complications, with the most common being defecation disorders (10.7%). Failure rates were found to be 8% (n=9). Surgical management was necessary for 5 patients (4.5%) who had mesh exposure. Of the 64 patients who were sexually active prior to surgery, 16.1% reported a decline due to de novo dyspareunia. De novo prolapse was seen in 13 patients (11.6%) in an initially non-treated compartment. Additionally, authors state that their results confirm the existence of a learning curve, with a significant difference in a surgeon with more than 10 surgeries.

14. dos Reis Brandao da Silveira (2015)

Authors aimed to compare the outcomes of native vaginal tissue repair with synthetic (Prolift) mesh repair in this multicenter randomized trial, which included 184 women with POP-Q stage 3 or 4. Repairs were anterior and/or posterior, and all patients with uterine prolapse received a hysterectomy. Follow-up consisted of clinic visits at 7, 30, 180, and 360 days. Ninety women were in the native tissue group, and 94 were in the mesh group. At one year, the only difference between the groups was related to mesh exposure, which occurred in 20% of patients in the mesh group, with a reoperation rate of 16.7%. The overall rate of reoperation in the native repair group was 3.7% (3 patients with recurrence), and 7.9% in the mesh group (2 patients with recurrence, 3 with exposure, 1 with wound dehiscence, and 1 with extrusion into the rectum).

Prolapse recurrence was observed in 16 patients from the native tissue group, and 7 from the mesh repair group.

15. Zhang (2015)

Investigators aimed to evaluate the incidence and predisposing factors of postoperative voiding difficulty and mesh-related complications in 206 women with stage III to IV POP who underwent a total Prolift repair in a prospective observational cohort study. The women underwent physical examination in the clinic at 3 months and every 12 months post-surgery. One hundred ninety-two women were enrolled in final data analysis and a mean follow-up period of 4.2 years (range 1 to 6 years). Bladder scan showed 60 of 192 (31.3%) of the women exhibited postoperative voiding difficulty (residual urine volume ≥ 100 mL or more than one third of voided volume), and 40 of 192 (20.8%) exhibited a residual urine volume of 200 mL or more. Twenty-nine of 192 (15.1%) reported mesh-related complications, and in most cases, women had more than one complaint. Mesh exposure and/or contraction were the most commonly reported (69%; 20 of 29). Of these, 80% (16 of 20) occurred more than 1 year after surgery. Dyspareunia was reported by 10% (2 of 20). There were 13 cases of mesh exposure that were repeated exposure which required excision. Authors suggest that women who had greater blood loss during the surgery or previous pelvic operations were prone to vaginal complications, and suggest this may be due to the presence of an increased number of scars caused by previous operations and the possibility of scar and hematoma formation impairing integration between the mesh and tissues. The authors also noted that blood loss and hysterectomy were strongly correlated. Four patients required sling surgery for SUI, all from the mesh group.

B. Prolift+M

1. Ignjatovic (2011)

This article reported the 1-year outcomes of a prospective study involving 32 patients who were implanted with Prolift+M anterior. At 1 year, POP was corrected (postoperative POP grade ≤1, the most distal point 1 cm above the level of the hymen) in 28 of 32 (87.5%) patients. Grade 0 was present in 23 of 32 (71.8%) and grade 1 in 5 of 32 (6.7%) of patients. Mesh erosion was reported in 9.3% of patients. Twenty-two patients (68.7%, mean age 53.6 years) were sexually active before the surgery and 21 (65.6%, mean age 53.2 years) after the surgery. The authors noted that postoperative sexual life could not be evaluated reliably because it was absent in a certain number of patients at the beginning of the study.

2. Milani (2011)

Milani, et al, published a prospective observational study involving 127 patients, 41 anterior, 16 posterior, and 70 total. The primary outcome was defined as anatomic success in the treated compartment at 1 year being a POP-Q stage I, without further surgical re-intervention. Anatomical success in the treated compartment was 77.4%. Of those patients without prolapse in the other compartment, 20.5% had de novo stage II prolapse develop in the untreated

compartment by 1 year. There was a statistically significant improvement in sexual function score in patients at both 3 months and 1 year post implant. At 1 year, 3.9% of patients reported pelvic pain. Thirteen patients or 10.2% had mesh exposure or erosion during year 1 with 7 undergoing mesh excision and 6 treated with topical estrogen.

3. Khandwala (2013)

This is a prospective study done in 157 consecutive subjects who were treated with the Prolift+M System, 104 total, 5 anterior, and 48 posterior, from April 2009 to November 2010. The subjects were followed at 6 weeks, 6 months, and 12 months postoperatively. 117 of the study participants had concomitant procedures, the treatment of stress urinary incontinence with TVT-O. Success was defined as a POP-Q score lower than Stage II and responses to questionnaires indicating that the patient did not have bothersome bulge symptoms and a feeling that they were "much better" post-implant. When assessed by preoperative POP-Q stage of prolapse, the composite scores were as follows: stage II, 85.3%; stage III, 88.9%; and stage IV, 89.5%. When assessed by the type of the Prolift+M mesh procedure, the breakup of the composite success scores were as follows: total, 88.6%; posterior, 86.4%; and anterior, 100%. If the lost-to follow-up subjects are considered failures, then the composite score would be 75.2% and the anatomic cure would be 80.3%. Three (2.2%) of 134 subjects had mesh exposure in the vagina. One subject underwent excision in the operating room, and 2 subjects were managed expectantly. De novo dyspareunia was noted in 3 (6%) of 50 subjects, only 37.3% of patients were sexually active preoperatively. De novo SUI was reported by 11 subjects (8.2%), and 15 subjects (11.2%) reported de novo urge urinary incontinence.

These studies raise red flags and, by no means, confirm the safety and efficacy of the Prolift and Prolift+M products.

VI. ETHICON DID NOT PERFORM PROPER CLINICAL TRIALS TO DEMONSTRATE THE SAFETY AND EFFICACY OF ITS DEVICES

From my review of the materials referenced, I was impressed by the clear absence of any systematic approach on the part of Ethicon with regard to the clinical testing of the products prior to placing the products on the market. Scott Jones acknowledged that one option available to Ethicon was to not make the Prolift commercially available until clinical trials could be conducted to establish that the Prolift product and procedure was safe and effective, but Ethicon chose to go directly to market:

> Q. Certainly one of the options to Ethicon would have been to not sell the Prolift® on a widespread commercial basis as it was and instead just limit it to experimental clinical trials until there could be solid confidence throughout the medical community that this was a safe and effective procedure and product. That was an option that Ethicon had. Correct?

A. I suppose it's always an option with any product or any company.

…

Q. Ethicon had the option to not make the Prolift® commercially available unless and until carefully controlled long-term clinical trials could prove it to be safe and effective enough to justify whatever risks there were, but rather, Ethicon chose not to do that, instead just sell it commercially as it did. Correct?

A. Ethicon did choose to commercially sell the product, if that's what the question is.[39]

The Prolift was not adequately studied before it was launched.

A critical analysis of these devices and how they would function inside a woman's body was never made before the devices were placed on the market. There were no proper randomized controlled trials with institutional review board (IRB) approval performed in the United States or abroad prior to selling these products.[40] Ethicon was aware of the lack of clinical data and the implications of not having this data. Support for this opinion is contained in Section VIII.c.

At the same time, Ethicon ignored significant evidence in the literature and their own experience with hernia mesh and Gynemesh PS mesh that would have led any reasonable person to expect the product to cause significant complications and risks.

The clinical studies Ethicon used to support the sale of the Prolift Systems are referred to as the French and US TVM studies and described above. These studies did not utilized the same mesh shapes,[41] instruments, or exact surgical procedures as the Prolift Systems. The TVM studies did not establish the safety and effectiveness of the Prolift Systems. The French TVM study failed its primary endpoint of 20% or less recurrence rate with only 1 year of follow-up, and the US TVM study met the endpoint by four-tenths of a percentage point only after Ethicon violated the original study protocol and changed the statistical parameters that defined failure versus success, in order to be able to falsely claim that at least one of the TVM studies was a success.

Overlaying these inadequacies was the complete lack of any long-term studies establishing the safety and effectiveness of the Prolift Systems. In an article accepted for publication on

[39] Jones dep., 727:19-728:4; 728:25-729:10.

[40] ETH.MESH.01160159, Gynemesh Prolene Soft mesh, pre-clinical functionality testing strategy, 11-1-2001, Conclusion: "Based upon the Gynemesh Prolene Soft mesh's product characteristics, intended clinical indications and the use of existing polymer materials, additional pre-clinical functionality testing is not required."

[41] This study, an open-label observational cohort without a control group, enrolled 90 patients from 8 sites in France and reported 12-month follow-up on 87 patients. Gynemesh PS mesh was provided by Ethicon and cut by the surgeons using a template into a shape resembling but not identical to that of the Prolift mesh implant. Although the surgeons were expected to cut the implant to the provided template, it later became evident that not all surgeons were adhering to this requirement and instead were hand-cutting the mesh implant without following the template. ETH.MESH.00401457 (Email 1-31-2006 about protocol violations, from Allie Smith: "On the French study some material was hand cut …").

September 14, 2006, and published thereafter in the International Urogynecology Journal, the French TVM Group recounted numerous complications, and concluded that long-term data were needed to establish the safety and effectiveness of the Prolift Systems – this 18 months after the Prolift Systems were first marketed.[42] Long-term studies establishing the long-term safety and effectiveness of the Prolift Systems were never conducted. Importantly, long-term studies that describe the safety and effectiveness of the Prolift Systems compared with traditional vaginal prolapse surgery were never performed.

If the Prolift System was to be used at all, it should only have been used in the context of a rigorous experimental clinical trial, under strict guidelines, with a limited and carefully selected patient population, and only with an extensive informed consent process designed to clearly notify participants that the use of the Prolift System was purely experimental, that the safety and effectiveness could not be reliably stated (hence, the need for clinical study), and that significant, life-altering complications could result, which could be untreatable.

Ethicon failed to establish a data registry for the Prolift that would have enabled it to track the results in real practice. Physicians providing feedback confirmed that data registries are more "reflective of real world experience," because: "Clinical studies use Tier 1 docs [doctors], real world experience is heavily weighted with the outcomes produced by Tier 2 and 3 doctors. Data registries more reflect the real world in the eye of many of those docs."[43] A registry would have been a very useful tool to track the outcomes of patients who underwent the Prolift procedure and permanent Prolift mesh implantation.

Ethicon resisted a proposal to start a Prolift registry in Australia, confirming in a July 13, 2006 email that this was rejected for commercial reasons. "Consequently, if none of our competitors are keeping registries, our complication data may appear increasingly accurate but with decreasing appeal…"[415]

As a physician, I expect companies to provide me with complete and accurate information. This cannot be accomplished without sufficient clinical data.

In order to evaluate these products in any meaningful way, the entire device and procedure should have been used in testing. Issues such as graft tension, maintenance of graft orientation, shrinkage tendencies, deformation of the mesh (folding, bending, bunching, and cording), potential nerve and blood vessel injuries, histologic indicators of immune and inflammatory reactions, and impact on sexual function, bladder, and bowel function should have been studied prior to introduction. Outcomes, complications, and the best ways of managing complications should have been resolved prior to marketing.

Documents supportive of this opinion can be found in Section VIII.c.

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[42] ETH-02358-02367, Fatton BF, Amblard JA, Dabadie CD, Debodinance PD, Cosson MC, Jacquetin BJ. Preliminary results of the Prolift technique in the treatment of pelvic organ prolapse by vaginal approach: a multicentric retrospective series of 110 patients. Int Urogynecol J 2006; 17: s357-360.
[43] ETH-49659.

VII. THE MEDICAL LITERATURE DOES NOT SUPPORT THE USE OF MESH KITS FOR THE SURGICAL TREATMENT OF PELVIC ORGAN PROLAPSE.

Synthetic mesh implanted in the vagina with a trocar-based, armed mesh kit such as the Ethicon Prolift products causes life-altering and sometimes permanent injury and disability without proven benefit. The literature now bears this out. Urogynecologists, especially those of us in academic positions and referral centers, spend a great deal of our time managing mesh complications and performing challenging and risky mesh removal surgeries.

I have reviewed the reliable scientific literature regarding the use of transvaginal mesh for prolapse repair. From these studies (and confirmed by my clinical experience), I have made the following conclusions regarding the efficacy of these products:

1. There is no good evidence supporting improved benefit in quality of life (QOL) or relief of symptoms *in any compartment* with the use of transvaginal mesh for the treatment of pelvic organ prolapse.
2. There is no reduction in reoperation rates for prolapse *in any compartment* with the use of transvaginal mesh for the treatment of pelvic organ prolapse.
3. There is no evidence of anatomic benefit with the use of transvaginal mesh for the treatment of pelvic organ prolapse in the posterior or apical compartments.
4. Initially it appeared as if there might be some *anatomic* benefit in the anterior compartment. These findings are now reliably disputed and any anatomic benefit obtained is frequently a result of scarring and at the expense of proper function.
5. The total number of reoperations is higher in mesh repairs due to the rate of surgeries for repair of complications.

I have made the following conclusions regarding the safety of these products from my review of the scientific literature:

1. Adverse events and complications are common.
2. Many of these complications do not occur with traditional prolapse repairs.
3. Many of these complications are life-altering and permanent, unlike those seen with traditional prolapse repairs.
4. Many of these complications require additional surgery which may *or may not* alleviate the symptoms - unlike traditional prolapse repairs.
5. Sometimes, multiple surgeries are required.
6. These complications can occur at any time – months or years after the original surgery, unlike complications occurring with traditional prolapse repairs.
7. Explant surgery, when indicated, is risky, difficult to perform, and may or may not alleviate symptoms.

I have concluded the following regarding the differences regarding the mesh complications and those associated with traditional surgery:

1. Many of the complications reported occur only with mesh. These include erosion and extrusion, mesh contraction syndrome, organ perforation from mesh, partner injury,

severe vaginal pain, granulomas, and need for multiple surgical procedures for removal and attempted relief of pain.

2. Mesh complications, as opposed to complications with traditional repairs, are likely to be more frequent and more severe. Examples include dyspareunia, de novo stress urinary incontinence, chronic pelvic pain, neuromuscular injury, and emotional sequelae.
3. Most mesh complications are more difficult to treat. This includes fistulae, bleeding, infection, bowel/bladder injuries, dyspareunia, pelvic pain, and recurrent prolapse.
4. The potential for complications lasts indefinitely because the synthetic mesh is permanent and virtually impossible to remove in its entirety.
5. Some risks are still unknown and cannot be known for many years to come.

These opinions are based on a broad familiarity with the medical literature. The FDA reached many of these same conclusions in its white paper on the use of transvaginal mesh dated July 2011. Additional publications have appeared in the literature since the time of its publication, offering further support for these opinions. (e.g. Abbott, 2014; Lee, 2014). In short, the risks of armed, trocar-based prolapse mesh kits (such as the Prolift and Prolift+M products) far outweigh any benefits.

VIII. EXAMPLES OF ETHICON DOCUMENTS SUPPORTING THESE OPINIONS

The following sections give examples of Ethicon documents I have reviewed which support my opinions, but the supportive documents are not limited to those that are shown below.

a. Complications Caused by the Prolift Devices Were Foreseeable

ETH.MESH.01220730: (2/10/2004)

- Erosion is still a primary concern because it is the symptom or result of the scar formation around and on the mesh. The identification of the collagen fibrils' orientation and eventual contraction will be the measurement of how well we are succeeding in reducing the scar formation. The two are both important and I would use one to identify the potential for the other in this early stage work.

- What are the other materials/construct ideas being considered by Gynecare as second generation products to Gynemesh PS?

Redacted

- Additionally, I am open to other alternate material suggestions.

Contraction of Scar Tissue

- Has contraction of scar tissue been reported with use of Gynemesh PS?
- Yes it has. However, the only way it is specifically identified is when the repair fails and the surgeon needs to re-operate. Otherwise the complications which could indicate scar contraction, such as pain or tension (i.e.pulling or pressure) in normal circumstances can not be directly identified as due to the contraction, because every thing is internal and can not be seen. Also, female sexual dysfunction due to pain can be attributed to an over tightening of the vaginal tissue or scar adhesions between the vagina and rectum or bladder.

ETH.MESH.00584846

From: Kammerer, Gene [ETHUS]
Sent: Mon, 10 May 2004 16:20:27 GMT
To: Melican, Mora [ETHUS] <MMELICAN@ETHUS.JNJ.COM>; Brown, Kelly [ETHUS] <KBrown8@ETHUS.JNJ.com>; Gosiewska, Anna [ETHUS] <AGosiews@ETHUS.JNJ.com>
CC: Walji, Zenobia [ETHUS] <ZWalji2@ETHUS.JNJ.com>
Subject: FW: Mesh for TVM

Here is some input from the Gynecare European unit regarding mesh used for pelvic floor repair. Pro. Jacquetin is the inventor of the Pelvic floor repair technique Gynecare will be marketing next year. We are working very closely with him and Dr. Cosson to develop it. Based on this information and other communications I have had it seems our competition is ahead of us in this area. We need to think about how we can fast forward this project, get more support from both Gynecare and Ethicon as well as quickly optimize the construction. Kelly, let's add this in to our meeting agenda tomorrow.

Gene
-----Original Message-----
From: Berthier, Ophelie [JNJFR]
Sent: Monday, May 10, 2004 11:39 AM
To: Walji, Zenobia [ETHUS]
Cc: Bonet, Giselle [ETHUS]; Kammerer, Gene [ETHUS]; Arnaud, Axel [JNJFR]
Subject: Mesh for TVM

Zenobia,

I know you are working on new mesh materials with Gene and I'd like to share with you the inputs of Pr Jacquetin and Dr Cosson.

Their main concern is now the shrinkage of the mesh which may lead to pain, dyspareunia...Indeed now that they have tremendously improved the technique and lowered the erosion rate what needs to be improved is the shrinkage of the mesh (in this case gynemesh soft).

ETH.MESH.00681364

From: Walji, Zenobia [ETHUS]
Sent: Tue, 07 Sep 2004 13:50:29 GMT
To: Bonet, Giselle [ETHUS] <GBonet3@its.jnj.com>; Bell, Steve [ETHIT] <SBell6@ethit.JNJ.com>
CC: Mahar, Kevin [ETHUS] <KMahar@its.jnj.com>; Breznak, Mike [ETHUS] <MBREZNAK@ETHUS.JNJ.com>
Subject: FW: Pelvic Floor Monthly - August Report - Next Gen Materials Progress

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Dear Giselle (and Steve),

(SENSITIVE AND CONFIDENTIAL INFORMATION - Please do not share with anyone without discussing with me first)
Ronnie, Gene and I have had several meetings with CBAT (Center for Biomaterials and Advanced Technology group) to review their lab learnings from investigating several composite materials and therefore provide some direction for a Next Gen Pelvic Floor Material:

A) GYNEMESH PS + Bovine Collagen/Gag Matrix (Integra = Advanced Wound Care product used for Burns patients)
B) GYNEMESH PS + Proceed (Interceed + PDS - FYI this is a composite mesh released by EPD)
C) GYNEMESH PS + Europa (35% PCL, 65% PGA = CBAT material)

The key insights related to orientation of the collagen fibrils and therefore characteristics that could positively improve/reduce tissue contraction around the mesh. GYNEMESH PS today has a "swirling effect" causing what doctors have expressed as "shrinkage or contraction of the mesh". It isn't the mesh that's contracting, its the tissue that seems to be "bunching" up resulting in the desire to have a more "tension-free" fixation.
Bottom line, if you have collagen trails in ONE Direction, it is likely to cause MORE contraction.
Therefore, collagen trails that are multidirectional/more random may be BETTER to reduce contraction.

ETH.MESH.00442831:

-----Original Message-----
From: Kammerer, Gene [ETHUS]
Sent: Tuesday, January 18, 2005 11:21 AM
To: Brown, Kelly [ETHUS]
Cc: Yang, Chunlin [ETUS]; Walji, Zenobia [ETHUS]; Engel, Dr. Dieter [ETHDE]; Holste, Dr. Joerg [ETHDE]; Parisi, Paul [ETHUS]
Subject: RE: Proposal for work with CBAT

Kelly,
Are we beginning to make the samples? If so, I think we were going to do the synthetic material first then the collagen. If help is needed, I am available.

On another note, I spoke with Prof Mauro Cervigni today. He is an Italian gynecologist. He uses Gynemesh and Pelvicol to do a tension free pelvic floor repair. We talked about his requirements for an ideal mesh, what problems he is having with his current materials, and a lot about his procedure and technique. Some important points which he made:
1) infection is present in 8% of his cases and leads to erosions, therefore an antibiotic action in the mesh is needed. Erosion is present in 10% to 8% of his cases. He always sees an low grade fever associated with erosion, whether or not the infection actually is detected.
2) faster tissue repair would prevent complications of erosion and Dyspareunia, the later generally caused by scar contraction
a. contraction pulls against the side wall and causes pain
b. it causes a hard tissue which can be felt by patient and sexual partner
c. it can lead to a balling up of the mesh which is very uncomfortable
d. it can lead to suture line dehiscence
e. it can lead to prolapse recurrence

ETH-18761 (January 18, 2005):

Thank you also for your notes on the conversation with Prof. Mauro Cervigni. I find the perceived correlations between infection, mesh acceptance/tissue healing and vascularity intriguing (particularly in light of our proposed test samples that may aid vascularity). I also find the comments about mechanical property needs to be useful. I would like to learn more about UltraPro Mesh - perhaps we can include it in our battery of samples at some stage. In general, I am always pleased to learn of the commonalities in surgeons' observations. Many of the points that Prof. Cervigni mentioned have been voiced by other surgeons which gives me a degree of confidence in considering these issues in our innovative efforts.

Kelly

ETH.MESH.04945233

-----Ursprüngliche Nachricht-----
Von: Kammerer, Gene [ETHUS]
Gesendet: Mittwoch, 13. April 2005 18:27
An: Barbolt, Thomas [ETHUS]; Holste, Dr. Joerg [ETHDE]; Dormier, Edward [ETHUS]; Batke, Boris [ETHDE]
Cc: Angelini, Laura [ETHIT]; Guidry, Cyrus [ETHUS]; Schwartz, Barbara [ETHUS]; Engel, Dr. Dieter [ETHDE]; Storch, Mark L. [ETHUS]; Savidge, Sandy [ETHUS]; Brown, Kelly [ETHUS]
Betreff: RE: ULTRAPRO vs PROLENE Soft Mesh
Vertraulichkeit: Vertraulich

Tom,
Regarding which attributes to investigate to show a difference between materials, I have this input. The issue which I am trying to investigate/solve is one of scar contracture around the mesh. In pelvic floor repair even with the PSM, we have seen some scar contracture which translates into procedural complications. I don't want to state % here because the situation which produces the complication is in itself complicated and specific to each patient. Also, most of the data comes from VOC and not our documented studies. However, it is important to know that the surgeons who are our consultants on the ProLift product are asking for a mesh which is better than PSM in this area.
The complications which are identified in the market are 1) recurrence of the prolapse 2) pain 3) stiffness 4) erosion and 5) discomfort during sex. The surgeons attribute these conditions to scar contracture. If we could find a way to reduce the scar formation by some % and subsequently the contracture it would give us a significant advantage over the competition as well as make the procedure better for the patient. One way to prove this is, as you stated, by identifying the tissue reaction attributes which are directly associated with scar formation and contracture. Start with in vitro studies and then in vivo studies to show a specific link and a clear

b. Ethicon Knew about Complications and Did Not Inform Doctors How to Manage Them

P1704.

Prolift®: experience of the University hospital of Clermont-Ferrand

Prospective study	**Prolift®: patients operated on between March 2005 and August 2006**
Follow-up	18 months [12-27]
Patients included -available for follow-up	125 patients 107 patients
Mean age	66.7 years [42-87]
Menopause - HRT	118 patients (94.4%) 29 patients (23.2%)
Previous POP surgery	37 patients (29.6%)
Previous hysterectomy	45 patients (36%)
Previous SUI surgery	23 patients (18.4%)
Surgical procedure	**Anterior Prolift: 32.8%** **Posterior Prolift: 16%%** **Total or Ant+Post Prolift: 51.2% (20.1% + 31.2%)**
Mesh exposure rate - 3 months - max f/u	**11.2%** **14%**
Painful mesh shrinkage	**19.6%**
Global objective success rate	**75.7%** **POPQ<2 (-1cm)**

P.1704, p.23

Functional results : painful mesh shrinkage

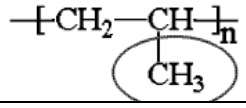
- Painful mesh shrinkage (at vaginal examination)
  - 21 patients (19.6%)
    - 13 sexually active
      - 5 without dyspareunia
      - 2 dyspareunie “often” (VAS 5 and 8 respectively)
      - 3 dyspreunia “sometimes” (VAS 5)
      - 3 didn’t complete the questionnaire
    - 8 sexually inactive
      - 1 became sexually inactive because of dyspareunia

Correlation between painful mesh shrinkage and dyspareunia but not systematic

ETH.MESH.02589066

Polypropylene can suffer from degradation following implant

- Polypropylene has a long history of use but it is subject to degradation; a process which initiates after a few days post implantation in animal studies[1]
  - This study proposes oxidation as the degradation mechanism, reporting that polypropylene filaments containing an antioxidant were less susceptible to oxidation
  - Oxidation usually occurs at the tertiary repeating position in the polymer, where a free radical is formed that then reacts with oxygen, followed by chain scission to produce aldehydes and carboxylic acids. In external applications, it shows up as a network of fine cracks that become deeper and more severe with time of exposure
  - Degradation of polypropylene has also been reported in the eye, where sutures were used to implant an intraocular lens[2] ; the authors suggest enzymatic degradation
  - Macrophages excrete acidic compounds that can initiate oxidation processes[4]
  - One clinician interviewed proposed that variability in the raw materials, and/or processing thereof, could be affecting the clinical performance and outcomes. He articulated his intention to investigate this hypothesis
  - High resolution images[3] of excised meshes clearly show physical degradation of polypropylene filaments



ETH.MESH.00031359

From: Vie, Amy [ETHUS]
Sent: Wed, 18 May 2005 00:16:20 GMT
To: Munchel, Kendra [ETHUS] <KMunchel@ETHUS.JNJ.com>; London Brown, Allison [ETHUS] <ALondon@ETHUS.JNJ.com>; Mahar, Kevin [ETHUS] <KMahar@ETHUS.JNJ.com>; Zipfel, Robert [ETHUS] <RZipfel@ETHUS.JNJ.com>; Campbell, Lori [ETHUS] <LCampbe3@ETHUS.JNJ.com>; Jones, Scott [ETHUS] <SJones34@ETHUS.JNJ.com>; Vasquez, Domingo [ETHUS] <DVASQUE1@ETHUS.JNJ.com>; Parisi, Paul [ETHUS] <PParisi@ETHUS.JNJ.com>; Kaminski, Marianne [ETHUS] <MKaminsk@ETHUS.JNJ.com>; Prine, Greg [ETHUS] <GPrine2@ETHUS.JNJ.com>
CC: Lane, Erika [ETHUS] <ELane@ETHUS.JNJ.com>; Chilcoat, Susie [ETHUS] <SChilco2@ETHUS.JNJ.com>; De Lacroix, Bruno [ETHUS] <BDelacr2@ETHUS.JNJ.com>; Castillo, Jeffrey [ETHUS] <JCastil9@ETHUS.JNJ.com>; Lech, Tom [ETHUS] <TLech@ETHUS.JNJ.com>
Subject: Summary of Prolift Training YTD

16 of the 84 have needed to be re-trained (19%), and all of these surgeons were first trained via cadaver labs. To my knowledge, we have not had a surgeon attend a preceptorship and request cadaver training.

ETH.MESH.00757011 [Note: Dyspareunia was not included in the 12/14/2007 IFU, it first appeared in 2009]

From: COSSON Michel <M-COSSON@CHRU-LILLE.FR>
Sent: Thu, 02 Feb 2006 09:39:34 GMT
To: Ciarrocca, Scott [ETHUS] <SCiarro2@its.jnj.com>; Bernard Jacquetin (E-mail) <bjacquetin@chu-clermontferrand.fr>; COSSON Michel <M-COSSON@CHRU-LILLE.FR>
CC: Robinson, David [ETHUS] <DRobin11@its.jnj.com>; Berthier, Ophelie [EESFR] <oberthie@its.jnj.com>; Bonet, Giselle [ETHUS] <GBonet3@its.jnj.com>
Subject: RE : PROLIFT Package Insert

Hi Scott
of course this warning is ok for me but probably it is a rare event, and we should add something about the potential pain or dyspareunia in the postoperative course ?
sincerely
michel cosson
-----Message d'origine-----
De : Ciarrocca, Scott [ETHUS] [mailto:SCiarro2@ETHUS.JNJ.com]
Envoyé : jeudi 26 janvier 2006 14:23
À : Bernard Jacquetin (E-mail); Michel Cosson (E-mail)
Cc : Robinson, David [ETHUS]; Berthier, Ophelie [ETHFR]; Bonet, Giselle [ETHUS]
Objet : PROLIFT Package Insert

Warm Greetings Professors Jacquetin and Cosson -

It has been too long since we have spoken or corresponded! Hope you are both well and had excellent holidays with your families.

We have just recently completed a comprehensive review of our PROLIFT complaint / complication database for 2006. You will be pleased (as we were) to know that our complaint rate for the system is extremely low. Discussions with our US clinical investigators have led us to consider 1 additional item under ADVERSE REACTIONS. Specifically the proposed wording of this addition is as follows:

"Dissection for Prolift and any similar procedure has the potential to impair normal voiding for variable length of time."

Could you please offer your opinion on this addition plus any other additions to ADVERSE REACTIONS or WARNINGS / PRECAUTIONS which may be appropriate?

Scott Ciarrocca

ETH.MESH.00870466

Ethicon Expert Meeting
Meshes for Pelvic Floor Repair
Friday, June 2, 2006; Location: Oststr. 1, Norderstedt, Meeting Room "Forum"

Vaginal pain after implantation of meshes is rare, but feared, since there is not real treatment option (V. Lucente: prefer 20 recurrences or Erosions over 1 pain patient)

ETH.MESH.00870466

Biological response to surgical mesh (Prof. Klosterhalfen)
Huge surface area of meshes (e.g. more than 300 m of suture)
Even after 20 years the tissue is still reacting to the mesh.
Fibrosis is responsible for complications in mesh usage. ' Redacted
compared to PP
Foreign body reaction:

- Fibrinogen and Albumin bind to biomaterial, change and activate the immunologic syster
- active process, a "chronic wound", to be demonstrated by proliferating and dying cells
- combination of material and genetics.

Optimum pore size is material dependent (critical pores size; at least 1-2mm), scar formation a combination of pore size, surface area, polymer.
Large pores: fibrosis on the mesh fiber only
Small pores: interconnection between mesh pores due to fibroses leading to mesh shrinkage.

Shrinkage of 20% means reduction of mesh area to 64%

Tension of the mesh changes pore size → change in elasticity
Films or Foils cause more shrinkage than meshes
Meshes can cause Nerve damage due to mechanical irritation (mesh bears on nerve)
There is no inert material

Unmet clinical needs	**Priority (points)**
No shrinkage / no long-term contraction Fibrosis reduction Severe contraction → Dyspareunia → sexual function ↓ *Tension response ↓* = ↓ *Sexual pain?* *No folding of mesh* *No rigidity*	10
No vaginal distortion, normal vaginal wall, maintain sexual function, normal sexual function	8

ETH.MESH.01184119

2009 Surgeon Summit Breakout Session – February 7
Survey Results

PROLIFT™ Pelvic Floor Repair Systems

The improvements requested for PROLIFT are mostly around training; this is felt to be a big need. There is not sufficient education regarding peri-obterator anatomy and there is a failure of surgeons to understand the anterior apical passage. Also, depth of dissection needs to be emphasized more. It was suggested that training should be tiered, and stage gates should be implemented, in which surgeons demonstrate an understanding of training prior to moving onto cadaver labs. Other areas of

ETH.MESH.02289896

ETHICON Women's Health & Urology

POP or PFTM?

- Post-op: Severe pain in LLQ, retention for 2 weeks and mesh exposure at 4 weeks
- Revision of exposure and DX LAPS at 6 weeks (adhesiolysis)
- Persistent pain, unable to have sex or stand for more than 1 hour due to pain, voids every 30-60 min
- Recurrent mesh exposure at 4 months

I have at least 4 pts with this problem sent to me. I feel that the pts start w/ mild POP and PFTM. The aggressive surgery flares the pre-existing myofascial pain. WE should therefore review with our doctors the difference between POP and the "pressure" of PFTM. POP does not cause pain!!! Look for symptoms >> degree POP

P1706 (June 2009)

Conclusion

Mesh shrinkage

- Is real !
- Occurs during the scarring and remodelling process
- May result in a unpredictable way in severe complications including dyspareunia, pain and recurrence
- May require mesh removal
- Must be taken into consideration during patient councelling before surgery

Is a challenge for the next years !

⇒ Need for a better understanding
⇒ Need for a better assessment
⇒ Need for a better material behaviour (and techniques)

ETH-80249

From: David Robinson
Sent: Friday, October 28, 2005 06:19 PM
To: Bonet, Giselle [ETHUS]
Subject: forgot

Dear Marty,
I know this will be my problem instead of yours soon but I need some advice. I am now aware of 4 cases of total Prolifts done in folks with normal preop voiding function (at least normal residuals and normal simple uroflows) who, then, post Prolift, can't void. Post op urodynamics show bladder atony rather than any obstruction. I have had two, Dennis Miller has at least one, and now Eric Webb called me with one today who is 5 weeks out. Some of these have resolved spontaneously but have taken as long as a year to do so.
Has this particular problem been reported? We are going to have to look at this because the cases seem to have no common thread or any difficulty with the surgery itself. But if this starts getting reported, it is going to scare the daylights out of docs.

ETH.MESH.04096233

-----Original Message-----
From: Chen, Meng [ETHUS]
Sent: Thursday, July 19, 2007 1:30 PM
To: Pelkey, Brian [ETHUS]; Yale, Mark [ETHUS]
Cc: Holloway, Carol [ETHUS]; Brennan, Carolyn [ETHUS]; Scavona, Joseph [ETHUS]
Subject: Prolift-post-op complication
Importance: High
Sensitivity: Confidential

Brian and Mark: Because a new case of ureter obstruction after Prolift just came in, and there were three others in my recollection, I would want to "cry wolf" once. I searched the Remetrex from March 06 to now. Out of 32 post-op complications, there are six ureter (the two channels bring urine to the bladder, not urethra) constriction or obstruction (including one bladder neck obstruction), about 20%. I am raising this issue to you for the following reasons:

1. Out of the 32 post-op complications, ureter obstruction should be considered the most serious. It could be rapid progressing to cause hydronephrosis and compromise renal function within a short period of time.
2. Ureter obstruction is not specifically mentioned as an adverse reaction in the Prolift IFU.
3. 20% of all post-op complication should be considered very significant, and my glance at all others, nothing else occupy such huge proportion.
4. From Dave's communications with the operating physicians, the doctors seemed not certain on how to diagnose and/or deal with the complication once confirmed.

5. It seems that because it is not listed in the IFU, there is no standardized or unified solutions, and Dave could not give specific advice. But the condition can be fast moving.

ETH.MESH.00133497 (Note: Voiding Dysfunction not added to IFU until 2009)

From: Robinson, David [ETHUS]
Sent: Mon, 21 Nov 2005 12:22:25 GMT
To: Selman, Renee [ETHUS] <RSelman@ETHUS.JNJ.com>; Hart, Dr. James [ETHUS] <JHart7@ETHUS.JNJ.com>; Mahar, Kevin [ETHUS] <KMahar@ETHUS.JNJ.com>; Staub, Linwood [ETHUS] <LStaub1@ETHUS.JNJ.com>; Bonet, Giselle [ETHUS] <GBonet3@ETHUS.JNJ.com>
CC: Weisberg, Martin [ETHUS] <MWeisbe1@ETHUS.JNJ.com>
Subject:

See attached summary of meeting at AAGL with Dennis Miller, Vince Lucente, Bob Rogers as consultants re: voiding probs post Prolift. As a consequence of this, Scott Ciarroca asked for wording to be added to the Adverse events section of IFU which I have suggested.
Dave

David Robinson, M.D., F.A.C.O.G.
Medical Director
ETHICON Women's Health and Urology

Discussion:
Any procedure which requires lateral dissection involving the pubocervical fascia (fascia endopelvina) or trigone puts the nerves of the bladder at risk for disruption. Seen by design in Ingleman-Sundberg operation which was done for refractory overactive bladder but isn't being performed any more since the nerves recovered within months of the procedure. The same process is being seen here but there is question as to whether the presence of the mesh in any way slows down the recovery. Other factors may further aggravate the voiding problem (general or epidural anesthesia, catheter use, anxiety). Recovery should occur spontaneously, though it might be months rather than weeks.

Conclusion:
This complication is not unique to Prolift but can occur with any procedure involving dissection described above. However, we should consider counseling our customers at the upcoming Prolift meeting so they will be able to counsel their patients appropriately and we need to check IFU for wording re: this problem. If need be, we should discuss whether to consider revising the IFU. Resolution should eventually occur spontaneously. Intermittant catheterization is an ideal management technique for this complication. Finally, we should consider performing animal studies (if an appropriate model can be found) to identify sites of nerve disruption and whether mesh retards recovery.

ETH.MESH.03923931 (Press Interview, Frankfort, June 9, 2005)

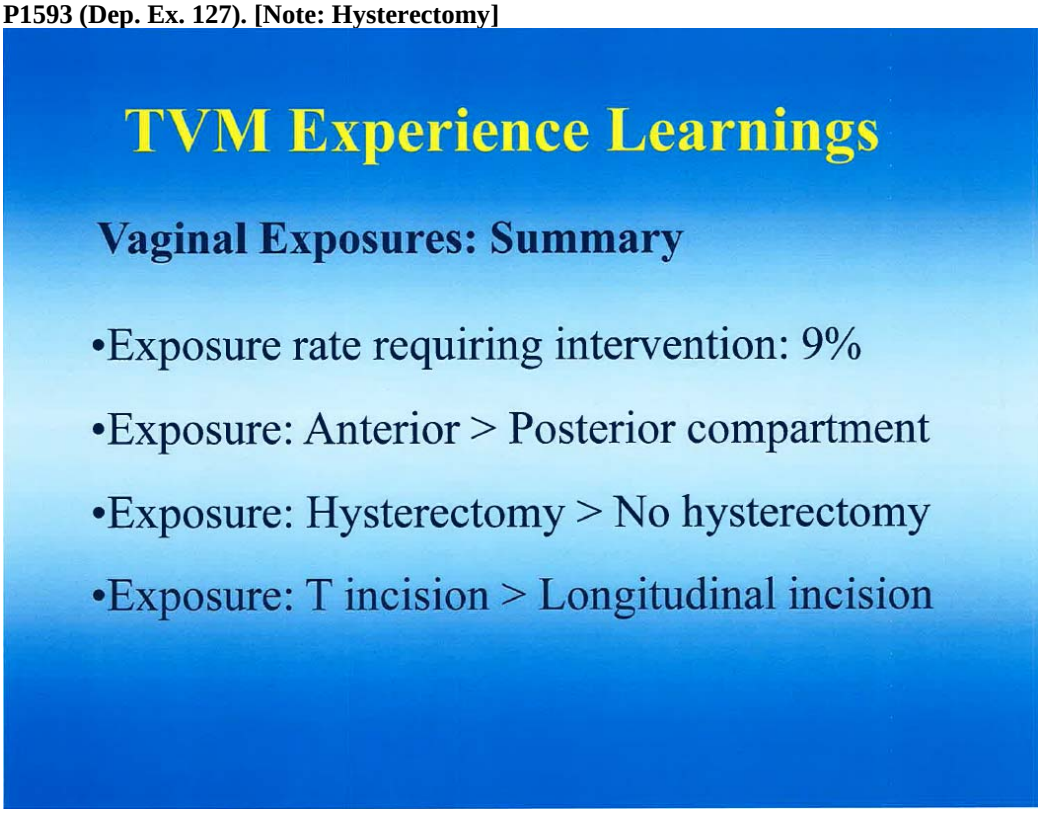
Comments

1. Mesh exposure is usually a minor complication. It can get cured most of the time by a simple excision of the part of the mesh that is apparent and a new vaginal closure.
Interestingly, the preliminary experience led to the identification of two key factors for the formation of an exposure:

- a concomitant hysterectomy:
- longitudinal incisions in the vagina.

Logically, the Group decided to change the type of the vaginal incisions and challenged the need for a systematic hysterectomy during prolapse surgery. This led to a dramatic decrease of the mesh exposure rate (<1%) when hysterectomy was not performed.
2. Shrinkage is due to an excessive scarring process. Even if most of the time it is asymptomatic, in a few cases it led to vaginal distortion impacting the sexual life. Thus, the procedure must be used cautiously in sexually active women.

P1593 (Dep. Ex. 127). [Note: Hysterectomy]



T-3321 (ETH.MESH.04082973) (Dep. of Meng Chen, MD, PhD)

Long term post-operative:

Persistent vaginal discharge (4.7%)
Vaginal bleeding (1.6%)
Dyspareunia (6.3%)
Sexual dysfunction
Recurrent prolapse (2.5%)
Mesh erosion (8.2%)
Obstructive voiding complications (11.0-18.3%)

Predictive Risk Factors for CV and Pulmonary Complications

- Age over 40
- Smoking history
- Obesity
- The presence of varicose veins

Other factors to consider

- Age
- Weight
- Parity
- Menopause status
- Estrogen therapy
- Previous surgeries
- Degree of pre-operative prolapse

c. Ethicon Did Not Perform Clinical Trials

ETH-00930

No clinical evaluations have been performed on the GYNECARE PROLIFT+M system. As PROLIFT+M is a Class II device (Product Code: FTL), demonstrating substantial equivalence to the predicate devices has been done with pre-clinical benchtop testing, and additional cadaver testing. This type of testing has been sufficient to demonstrate substantial equivalence for the identified predicates devices.

ETH.MESH.03915790

-----Original Message-----
From: Arnaud, Axel [ETHFR]
To: Azam, Usman [ETHUS]; Robinson, David [ETHUS]; Foltyn, Ted [ETHUS]
Sent: Mon Nov 13 11:41:23 2006
Subject: Pelvic Floor/Mesh Strategy

Oz/Dave/Ted

Some thoughts I could not pass during our call on friday:

1. Lightning
We should not forget the rationale behind this project. We set up a meeting with some experts, including I. Deprest and we asked them how we could improve the Prolift mesh. It came up that there are two issues with Prolift: erosion and shrinkage. Regarding erosions, whether a change in the mesh could result in any improvement is unknown as there is no certitude that the problem is mesh-related. It could as well be a surgical issue. The responsibility of the mesh seems to be more established regarding shrinkage and further to the expert's discussion, it was speculated that Ultrapro could be a solution for this problem, which is less common but can be more severe than erosion.

ETH.MESH.03915790 (continued)

I am a bit frightened to see that we are currently building a full business story on that, not having yet validated the proof of concept, neither from animal experiments nor from clinical use.
In my opinion, a logical way to proceed would be 1) to ask Deprest, for example, to compare Lightning and Gynemesh in animals and tell us if the theoretical assumption of less shrinkage is likely to be true 2) if this would be the case, we could then move on to clinicals and perform an observational study to confirm the benefits in humans 3) we could then discuss the need for a formal RCT to compare the two meshes and generate evidence that Lightning is a better choice than Gynemesh.
Alternatively, we could skip 1) and move directly to 2). If we ended up with results that would look better or at least equal to Gynemesh, we could certainly introduce the product on the market with a good chance of success (if reasonably priced) since the concept of light mesh is appealing on a surgical standpoint. If we are successful on the market, it is very unlikely that we will need to set up any RCT.
Finally, we could skip 1) and 2) and go directly for a comparative study. I do not believe this would be the best option, as it seems to me it would be expensive, long and risky.
To summarize, I support the idea of a single arm observational study.

P1143 (ETH.MESH.02923305)

From: Doherty, Anne [ETHGB]
Sent: Mon, 15 Aug 2005 09:55:55 GMT
To: Hunsicker, Kimberly [ETHUS] <KHunsick@ETHUS.JNJ.com>
Subject: FW: PROLIFT

FYI
-----Original Message-----
From: Linda Cardozo [mailto:lcardozo@compuserve.com]
Sent: 15 August 2005 10:53
To: ADohert1@ethgb.JNJ.com; anthony.smith@cmmc.nhs.uk; abdul.sultan@mayday.nhs.uk; ranee.thakar@mayday.nhs.com; mairecasement@hotmail.com; david.richmond@lwh-tr.nwest.nhs.uk; liz.adams@lwh-tr.nwest.nhs.uk; philip.toozs-hobson@bwhct.nhs.uk; chris.landon@leedsth.nhs.uk; tim@tsayer.co.uk; alfred.cutner@uclh.org; ian.ramsay@sgh.scot.nhs.uk; a@monga1.fsnet.co.uk; s_bjoornsson@msn.com
Cc: whitehead.whitehead@cmmc.nhs.uk; colette.davies@lwh-tr.nwest.nhs.uk; tina.cooper@nhht.co.uk.jnj.com; lindsey.dodds@leedsth.nhs.uk
Subject: RE: PROLIFT

Dear All

I have now had an opportunity to look at the complications associated with the TVM procedure. As I am not going to be able to attend a meeting in the afternoon of Tuesday 13th August in Montreal because of ICS commitments I thought I would just let you know that I find the safety profile quite worrying and hope that this will be discussed in some detail especially in view of the fact that we have no efficacy data to review. It is not that there were a lot of complications, its severity and type of complications and these were just the peri operative ones! I still have major concerns regarding the erosion rate and possible problems with dyspareunia and none of these have been addressed in the data which we have been given to date.

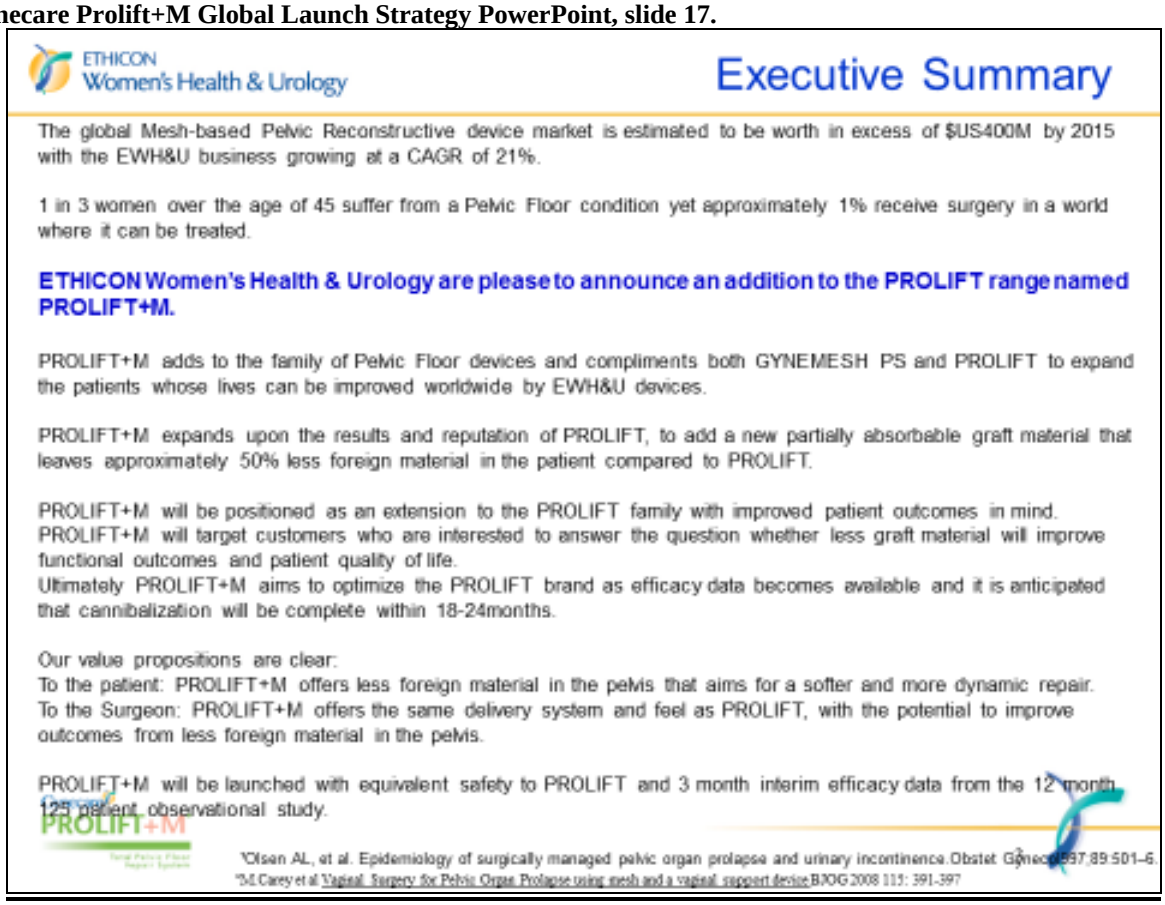
Unfortunately I am unable to attend the training sessions in Lille on either September 27th or October 25th but obviously I would wish to avail myself of a training opportunity if we are going to embark on a trial.

If the meeting does go ahead in Montreal please keep notes for me and let me know what your decision is as I would tend to be guided by the majority!

Kind regards

Linda

Gynecare Prolift+M Global Launch Strategy PowerPoint, slide 17.



ETHICON Women's Health & Urology

Executive Summary

The global Mesh-based Pelvic Reconstructive device market is estimated to be worth in excess of $US400M by 2015 with the EWH&U business growing at a CAGR of 21%.

1 in 3 women over the age of 45 suffer from a Pelvic Floor condition yet approximately 1% receive surgery in a world where it can be treated.

ETHICON Women's Health & Urology are please to announce an addition to the PROLIFT range named PROLIFT+M.

PROLIFT+M adds to the family of Pelvic Floor devices and compliments both GYNEMESH PS and PROLIFT to expand the patients whose lives can be improved worldwide by EWH&U devices.

PROLIFT+M expands upon the results and reputation of PROLIFT, to add a new partially absorbable graft material that leaves approximately 50% less foreign material in the patient compared to PROLIFT.

PROLIFT+M will be positioned as an extension to the PROLIFT family with improved patient outcomes in mind.
PROLIFT+M will target customers who are interested to answer the question whether less graft material will improve functional outcomes and patient quality of life.
Ultimately PROLIFT+M aims to optimize the PROLIFT brand as efficacy data becomes available and it is anticipated that cannibalization will be complete within 18-24months.

Our value propositions are clear:
To the patient: PROLIFT+M offers less foreign material in the pelvis that aims for a softer and more dynamic repair.
To the Surgeon: PROLIFT+M offers the same delivery system and feel as PROLIFT, with the potential to improve outcomes from less foreign material in the pelvis.

PROLIFT+M will be launched with equivalent safety to PROLIFT and 3 month interim efficacy data from the 12 month 125 patient observational study.

PROLIFT+M

[1]Olsen AL, et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501–6.
[2]M Carey et al Vaginal Surgery for Pelvic Organ Prolapse using mesh and a vaginal support device BJOG 2008 115: 391-397

ETH.MESH.00075065

-----Message d'origine-----
De : Robinson, David [ETHUS]
Envoyé : vendredi 13 juillet 2007 20:27
À : Berthier, Ophelie [ETHFR]; Lisa, Bryan [ETHUS]; Subramanian, Dhinagar [ETHGB]; Shen, Jessica X. [ETHUS]; Guidry, Cyrus [ETHUS]; Gauld, Judith [ETHGB]
Cc : Zaddem, Vincenza [ETHUS]; Meek, Jonathan [ETHUS]
Objet : RE: Lightning Launch Planning Stage Gate Preparation

Dear Ophelie

I have met with Judi Gauld, Jessica Shen and Bob Roda this morning. Part of the discussion centered on your question regarding what will be available at the time of the launch of Lightening. Your email quoted the May/June time frame as the launch date. Is this the date of the planned European NTM?
After presenting options to the Board, the Board made the decision to launch with only soft or no data depending on what time frame you consider. The planned observational study will collect 3 month data on all 60 patients which we would submit to IUGA for consideration in 3/08. Obviously, if accepted and then once presented and copy reviewed, it can be used internally and externally. Once submitted to IUGA, we believe it can be used in sales pieces by referencing "data on file" but nothing will be available to leave with doctors.
As I understand it, the "pre-launch" activities will involve limited KOL use as early as 11/07 if product is available. That would be done with previous UltraPro hernia data. Additionally, a further "limited launch" would occur following the US NTM date TBD, again with previous UltraPro hernia data.
I hope this helps clarify the picture.
Dave

P.1659 (Characteristics of Synthetic Materials Used in Prolapse . . . Surgery)

It is a challenging task to try to define the ideal material for pelvic floor surgery. Indeed, the scientific knowledge about the use of meshes in surgery is still in its infancy, at least for pelvic floor applications. There are far more products available on the market than randomized comparative trials which could help making a clear distinction among them.

In the absence of strong clinical evidence, one have to rely on various sources to try to help the surgeons to make an appropriate choice when considering the use of a synthetic material. These are essentially: basic knowledge from the science of textiles, clinical and fundamental research from hernia surgery and results of the more recent clinical experience in pelvic floor reconstruction.

Thus, all the recommendations that might be given in this presentation must be viewed with respect to these difficulties of finding hard data. They should certainly be reconsidered on a regular basis as long as more evidence is made available by the searchers.

ETH.MESH.03916207

From: Berthier, Ophelie [ETHFR] <OBERTHIE@jnjfr.jnj.com>
Sent: Thu, 12 Jul 2007 11:15:04 GMT
To: Robinson, David [ETHUS] <DRobin11@ETHUS.JNJ.com>; Lisa, Bryan [ETHUS] <BLisa@ETHUS.JNJ.com>; Subramanian, Dhinagar [ETHGB] <DSubrama@ethgb.JNJ.com>; Shen, Jessica X. [ETHUS] <JShen@ETHUS.JNJ.com>; Guidry, Cyrus [ETHUS] <CGUIDRY2@ETHUS.JNJ.com>; Gauld, Judith [ETHGB] <JGauld@ethgb.JNJ.com>; Arnaud, Axel [ETHFR] <AARNAUD@jnjfr.jnj.com>
CC: Zaddem, Vincenza [ETHUS] <VZaddem@ETHUS.JNJ.com>; Meek, Jonathan [ETHUS] <JMeek1@ETHUS.JNJ.com>; Burns, Janice [ETHGB] <JBURNS5@ethgb.jnj.com>; St. Hilaire, Price [ETHUS] <PSTHILAI@ETHUS.JNJ.com>
Subject: RE: Lightning Launch Planning Stage Gate Preparation

---

Dave,
Thanks for responding quickly. Does that mean that if the abstract is refused, we will have no data to communicate to the salesteams?

In addition, I am still not clear what exactly we will be able to provide salesforce for their training and external customer once we launch from the Lightning clinical study. Because even if we don't have massive data to show customers, being able to provide at least some mesh exposure or erosion rate will be something we will need, nb of patients, immediate post op complications and per op complications will be useful to launch properly Prolift+M. Do you who could help there?

Bryan,
Can't we use data with the quote "internal file data" to issue a powerpoint slide or two with few datas to comunicate to our salesforce and customers?

Thanks a lot for your help and support,

Ophélie

ADDITIONAL DISCLOSURES

I may be asked to review additional materials and/or documentation as the case progresses and, in that event, I reserve the right to supplement this report. My current hourly fee is $650/hour, not including testimony.

During the previous four years, I have testified as an expert witness at deposition or trial in the following cases:

In re: C.R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2187 (S.D. W.Va.)
Nava v. Boston Scientific Corp., et al., Civ. Action No. 2:13-cv-14455 (S.D. W.Va.)
In re: Boston Scientific Corp., MDL No. 2326 (S.D. W. Va.)
Callen v. C.R. Bard, Inc., Civ. Action No. 2:14-CV-14375 (S.D. W. Va.)
Harrison v. C.R. Bard, Inc., Civ. Action No. 2:12-CV-06602 (S.D. W. Va.)
Huber v. C.R. Bard, Inc., Civ. Action No. 2:13-CV-02424 (S.D. W. Va.)
Jay v. C.R. Bard, Inc., Civ. Action No. 2:13-CV-08536 (S.D. W. Va.)
Rueda v. C.R. Bard, Inc., Civ. Action No. 2:13-CV-02175 (S.D. W. Va.)
Smitty v. C.R. Bard, Inc., Civ. Action No. 2:13-cv-33750 (S.D. W. Va.)

This 1st day of February, 2016.

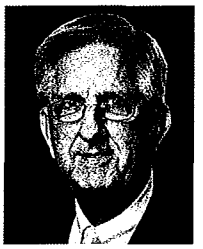
Bob L Shull MD.

Bob Shull MD

Exhibit A

CURRICULUM VITAE

BOBBY LEWIS SHULL, M.D.



ADDRESS: **Home:** 1519 Hilltop Circle
Salado, Texas 76571
Phone: 254-773-1217

Office: Scott & White Clinic and Hospital
Department of Obstetrics and Gynecology
2401 S. 31st Street
Temple, Texas 76508
Phone: (254)724-5872 Fax: (254)724-8927
E-Mail: bshull@swmail.sw.org
Beeper: 0685

PERSONAL INFORMATION:

Born March 20, 1943, in Shelby, North Carolina
Married (Sara Shull) three children (Margaret, Kathryn, Andrew)

EDUCATION

College: Duke University, Durham, North Carolina, 1961-64
Medical School: Tulane University, New Orleans, Louisiana, 1964-68 - M.D.

POSTGRADUATE TRAINING: (Obstetrics and Gynecology)

Internship: University of Virginia, Charlottesville, Virginia, 1968-69.
Residency: University of Virginia, Charlottesville, Virginia, 1969-1973.

PROFESSIONAL APPOINTMENTS:

CURRENT POSITION:

Professor, Division of Gynecology
Chief, Section of Urogynecology and Reconstructive Pelvic Surgery
Department of Obstetrics and Gynecology
Scott and White Clinic & Memorial Hospital
Texas A&M System Health Science Center College of Medicine

STAFF APPOINTMENTS:

Sheppard Air Force Base Regional Hospital, Wichita Falls, Texas, 1973-75
Chief of Obstetrics and Gynecology, 1973-1975
Scott and White Clinic, Temple, Texas, 1975-present
Director, Division of Gynecology, January, 1983-1997
Chief, Section of Urogynecology and Reconstructive Pelvic Surgery

Texas A & M System Health Science Center College of Medicine, faculty, 1978 - present
Associate Professor, 1981-1985
Professor, March, 1985 - present
Trustee, Scott and White Hospital, January 1993 - present

BOARDS: American Board of Obstetrics and Gynecology, 1975
ABOG Recertification, June 30, 1986 and 1996

LICENSE: Texas and Louisiana

HONORS:

President, Texas Association of Obstetricians & Gynecologists, 1986-1987
President, North American Obstetrical and Gynecological Society, 1988-1989
President, University of Virginia Obstetrical-Gynecological Society, April, 1988
President, American Urogynecologic Society, 1996-1997
President, Society of Gynecologic Surgeons, 2001-2002
Patron, Urogynecologic and Reconstructive Pelvic Surgery Society of India, 2006 - present
Elected to Alpha Omega Alpha, ETA Chapter, Texas A&M College of Medicine, April, 1988
Reviewer, Obstetrics and Gynecology, 1988-present
Reviewer, American Journal of Obstetrics and Gynecology, 1990-present
Reviewer, Texas Medicine
Associate Examiner, American Board of Obstetrics and Gynecology, 1991 - present
Editorial Board, Journal of Pelvic Surgery
Reviewer, New England Journal of Medicine, 1996-
Reviewer, International Urogynecology Journal, 1996
Honorary Fellow, Royal Australia and New Zealand College of Obstericians and Gynaecologists, 2011

AWARDS:

1. Certificate of Merit Award, Central Association of Obstetricians - Gynecologists, "Bilateral Attachment of the vaginal cuff to iliococcygeus fascia: an effective method of cuff suspension", Shull BL, Capen CV, Riggs M, Kuehl T, Chicago, Illinois, October 1992.

2. Outstanding manuscript, The American Urogynecologic Society Annual Meeting, "The squirrel monkey: An animal model of pelvic relaxation", Coates KW, Galan HL, Kuehl TJ, Shull BL, San Antonio, Texas, November 1993.

3. Presidential Prize Paper, The Society of Gynecologic Surgeons, "Surgical management of prolapse of the anterior vaginal segment: an analysis of support defects, operative morbidity, and anatomic outcome", Shull BL, Benn SJ, and Kuehl TJ, Nashville, Tennessee, March, 1994.

MEDICAL AND PROFESSIONAL ACTIVITIES:

Societies: Fellow, American College Obstetricians and Gynecologists, 1975-present
American Medical Association
American Fertility Society
Association of Professors of Gynecology & Obstetrics, 1978-1986
Council on Resident Education in Obstetrics and Gynecology, 1980-86
North American Obstetrical and Gynecological Society
Texas Association of Obstetricians and Gynecologists
Texas Medical Association
Texas Civil Justice League, Board of Directors
Bell County Medical Society
University of Virginia - Obstetrical-Gynecological Society
Society of Gynecologic Surgeons
Society of Air Force Clinical Surgeons
Central Association Obstetricians & Gynecologists
American Urogynecologic Society
International Continence Society
Central Travel Club

Committees: **Scott and White Clinic and Hospital**
Residency Program Director, June, 1980-June, 1986
Member, Program Directors' Committee, 1980-1986
Personnel Committee
Operating Room Services Committee, 1987-present
Surgical Case Review Committee, Chairman, 1987-1993
Procedures Committee
Social Committee, Co-Chairman
Clinicopathology Committee
Clinic Staff Organization
President, 1984-85
Chairman, Fringe Benefits Committee, 1982-1987
Professional Advocacy Committee, Chairman, 1983-present
Access and Advisory Committee, Scott and White Health Plan
Growth Strategies Planning Team, 1993
Trustee, Scott, Sherwood and Brindley Foundation and Executive Committee
Hospital Board of Trustees, 1993 - 2002
Secretary - Treasurer, 1995 - 1996
First Vice President 1997
Treasurer 1998
Credentials Committee

Texas A&M System Health Science Center College of Medicine
Curriculum Task Force on Preventive Medicine, 1981-1982
Course Director, Senior Elective in Ambulatory OB/GYN, 1980-1982
Department Education Coordinating Committee, 1987-present

Task Force on Teaching in the Ambulatory Setting, 1988-present
Chairman, Search Committee for Anesthesia Chair, 2000-2001

American Board of Obstetrics and Gynecology
Associate Board Examiner, 1991-present

American College of Obstetricians and Gynecologists
Committee Chairman, District VII ACOG, Special Interest Group in Reproductive Endocrinology, 1979
State Legislative Designee, 1986 - present
Vice Chairman, Texas Section, A.C.O.G., October, 1992-October, 1995
Chairman, Texas Section, A.C.O.G., 1995 – 1998
Member, Review Committee, PROLOG Test Booklet "Gynecologic Surgery and Oncology", Washington, DC, 1999

American Uro-Gynecologic Society
Vice President, 1994-95
President Elect, 1995-96
President, 1996 - 97

Central Association of Obstetricians/Gynecologists
Board of Directors, 1994 - 1996

Society of Gynecologic Surgeons
Executive Committee, 1993-1995
Vice President, 2000-2001
President, 2001-2002

Texas Association of Obstetricians/Gynecologists
Executive Board member, March 1982-1988
President, 1986-87

Texas Medical Association
Perinatal Committee, 1986-1992
Maternal-Child Health Committee, 1986-1992
Secretary, Section of Ob/Gyn, 1991-92

Urogynecologic and Reconstructive Pelvic Surgery Society of India
Patron, 2006 - present

World Health Organization
Chairman Sub-Committee on Physical Examination
First International Consultation on Continence

Liaison Committee in Medical Education
Appointed member, OB/GYN Division, 2001-present

RESEARCH PROJECTS:

1. "Randomized Prospective Comparison of Laparoscopic-Burch Urethropexy with Standard Transabdominal Burch Urethropexy for the Treatment of Genuine Stress Incontinence", co-investigator, 1994.
2. EW Higgins, PM Yandell, BL Shull, HT Papaconstantinou: Coexistent Rectal and Vaginal Prolapse: Report of a Case Series of Combined Surgical Repair Utilizing a Perineal Approach. No Funding Required.
3. EW Higgins, PM Yandell, TJ Kuehl, BL Shull: Use of graft materials in transvaginal pelvic reconstructive surgery: A survey of attitudes, judgments and practice patterns among urogynecologists. No Funding Required.
4. JB Bracken, M Rankin, JM Gendron, LM Pierce, VM Runge, BL Shull, TJ Kuehl: Serial Magnetic Resonance Imaging of Primiparous Squirrel Monkeys Demonstrates Pelvic Floor Muscle Change. Funded by TJK's Chair Account
5. ND Livers, ET Bird, PM Yandell, TW Muir, BL Shull, KP McMorries, TJ Kuehl, RK Huffaker: Does Body Mass Index Impact Successful Voiding Following Midurethral Sling Procedures for Stress Urinary Incontience. No Funding Required
6. EW Higgins, PM Yandell, JN Bracken, TJ Kuehl, BL Shull: Does Post-Operative Prophylaxis with Macrobid Reduce the Incidence of Post-Operative Urinary Tract Infection in Patients Undergoing Placement of Mid-Urethral Sling for the Treatment of Stress Urinary Incontinence: A Randomized, Double Blinded, Placebo Controlled Clinical Trial- Departmental Research Funded
7. JB Bracken, EW Higgins, PM Yandell, TJ Kuehl, BL Shull: Randomized controlled trial of local anaesthesia versus saline with effect on post operative urinary retention after TVT midurethral sling. Departmental Research Funded
8. DH Tran, JN Bracken, PM Yandell, TJ Kuehl, BL Shull: Transvaginal Repair of Failed Abdominal Sacral Colpopexy Utlilizing Graft: Case Series. No Funding Required.
9. C Chung, PM Yandell, TJ Kuehl, BL Shull: Retrospective multi-center case-control study assessing risk factors for the development of postoperative voiding dysfunction following miduretral sling placement. No Funding Required
10. C Chung, PM Yandell, BL Shull, WI Larsen, TJ Kuehl: The Impact of Age on Pain Management after Pelvic Reconstructive Surgery: A Retrospective Study No Funding Required
11. C Chung, PM Yandell, R Miskimins, TJ Kuehl, BL Shull: Association of outcomes to choice of apical support suture type in uterosacral ligament suspension procedures. No Funding Required
12. C Chung, PM Yandell, TJ Kuehl, BL Shull: Risk Factors for synthetic Mesh Extrusion Following Abdominal Sacral Colopexy and Vaginal Mesh Procedures: A Retrospective Study. No Funding Required.

PUBLICATIONS: PEER REVIEW

1. Shull B, Haskins T: Adnexal torsion - A mind-twisting diagnosis. So Med Journ, 79(5):576, May, 1986.

2. Shull BL, Verheyden, CN: Combined plastic and gynecological surgical procedures. Annals of Plast Surg, 20 (6):552, June 1988.

3. Shull BL, Taylor PT: Testicular feminization syndrome: A case study of four generations. So Med Journ, 82(2):251, 1989.

4. Shull BL, Baden WF: Paravaginal defect repair for urinary incontinence: A six year experience. Am J Obstets Gynecol 1989; 160(6):1432-40.

5. Hampton CR, Shull BL: Entero-uterine fistulae: Two rare cases of intestinal neoplasms manifested by gynecologic symptoms. Southern Med J, 1990;83(2):235-38.

6. Shull BL, McMillion JS: 46,XY Gonadal dysgenesis: Three case reports demonstrating an evolution in management. Texas Medicine, 1990; 86(11):64-67.

7. Shull BL: Using videography to teach retropubic space anatomy and surgical technique Obstets Gynecol, 1991, 77(4):640-41.

8. Shull BL: Surgery for urinary incontinence - excluding stress. Current Opinions in Obstetrics and Gynecology, 1991, 8.

9. Shull BL, Capen CV, Riggs M, Kuehl T: Pre- and postoperative analysis of site-specific pelvic support defects in 81 women treated by sacrospinous ligament suspension and pelvic reconstruction. Amer J Obstet Gynecol, 1992: 166(6-1):1764-68.

10. Shull BL, Capen CV, Riggs M, Kuehl T: Bilateral attachment of the vaginal cuff to iliococcygeus fascia: an effective method of cuff suspension. American J Obstets Gynecol, 1993, 168:1669-77.

11. Sulak PJ, Kuehl TJ, Shull BL: Vaginal pessaries and their use in pelvic relaxation. Journal of Reproductive Medicine, 1993, 38:919-923.

12. Shull BL: Clinical evaluation of women with pelvic support defects. Clinical Obstet Gynecol, 1993, 36:939-951.

13. Shull BL, Benn SJ, Kuehl TJ: Surgical management of prolapse of the anterior vaginal segment: an analysis of support defects, operative morbidity, and anatomic outcome, Am J Obstet Gynecol 1994;171:1429-39.

14. Coates KW, Galan HL, Kuehl TJ, Shull BL: The Squirrel Monkey: An Animal Model of Pelvic Relaxation. Amer J Obstet Gynecol, 1995;172:588-593.

15. Coates KW, Gibson S, Williams LE, Brady A, Abee CR, Shull BL, Kuehl TJ: The squirrel monkey as an animal model of pelvic relaxation: An evaluation of a large breeding colony. Amer J Obstet Gynecol, 1995; 173:1664-1670.

16. Shull BL: How I do the abdominal paravaginal repair. Journal of Pelvic Surgery, 1995;1:43.

17. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JOL, Klarskov P, Shull BL, Smith ARB: The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol, 1996;175:10-7

18. Weary KP, Coates KW, Shull BL, Yandell PM, Huddleston KP, Kuehl TJ: Laparoscopic release of unilateral postoperative ureteral obstruction. Journal of Pelvic Surgery, 1996; 2(2):72-75.

19. Coates KW, Shull BL: Paravaginal Defect Repair. Operative Techniques in Gynecologic Surgery, 1997; 2(1):31-34.

20. Shull BL. Pelvic organ prolapse: anterior, superior and posterior vaginal segment defects. Am J Obstets Gynecol 1999;181:6-11.

21. Summitt RL, Lucente V, Karram MM, Shull BL, Bent AE. Randomized comparison of laparoscopic and transabdominal burch urethropexy for the treatment of genuine stress incontinence, Obstets Gynecol 2000; 95 (1SUP4):S2

22. Shull BL, Bachofen CG, Coates KW, Kuehl TJ. A Transvaginal Approach to Repair of Apical and Other Associated Sites of Pelvic Organ Prolapse Using Uterosacral Ligaments. Am J Obstet Gynecol, 2000: 183;1365-1374.

23. Shull BL. Clinical Evaluation and Physical Examination of the Incontinent Woman. Journal of Pelvic Surgery, 2000; 6(6): 334-343.

24. Coates KW, Kuehl TJ, Bachofen CG, Shull BL. Analysis of surgical complications and patient outcomes in a residency training program. Am J Obstet Gynecol 2001; 184:1380-5

25. Shull BL, et al. PROLOG Task Force for Gynecologic Oncology and Surgery, Fourth Edition, American College of Obstetricians and Gynecologists, Washington, DC, 2001

26. Sulak PJ, Kuehl TJ, Ortiz M, Shull BL: Acceptance of Altering the Standard 21 day/7 day Oral Contraceptive Regimen to Delay Menses and Reduce Hormone Withdrawal Symptoms. Am J Obstet Gynecol 2002; 186: 1142-1149.

27. Vineyard DD, Kuehl TJ, Coates KW, Shull BL: A comparison of preoperative and intraoperative evaluations for patients who undergo site-specific operation for the correction of pelvic organ prolapse. Am J Obstet Gynecol 2002; 186: 1155-1159.

28. Shull BL. Equilibrium – Presidential address. Transactions of the Twenty-eighth scientific meeting of the Society of Gynecological Surgeons. Am J Obstet Gynecol 2002; 187: 1431-33.

29. Shull BL. A Cullen Richardson: Noticer, pioneer, mentor, and friend. Presented at the Sixty-Fifth Annual Meeting of the South Atlantic Association of Obstetricians and Gynecologists, Hot Springs, Ark, January 25-28, 2003. Am J Obstet Gynecol 2003; 189:403-7.

30. Brubaker L, Shull B. EGGS for patient-centered outcomes. Int Urogynecol J (2005) 16: 171-173.

31. Shull BL, Karram MM. Concerns regarding pelvic reconstructive surgery. Int Urogynecol J (2005) 16:251-252.

32. Kramer LA, Gendron JM, Pierce LM, Runge VM, Shull BL, Kuehl TJ. Magnetic resonance imaging of the levator ani in the squirrel monkey: a comparison of muscle volume between a cohort with pelvic organ prolapse and matched normals. AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY 2006; 194:1467-71.

33. Shull BL, Foster R. The Ulf Ulmsten Lecture presented at the opening ceremonies of the 30th Annual congress of the International Urogynecologic Association – August 10, 2005, Copenhagen, Denmark. Int Urogynecol J (2006) 17:430-435.

34. Huffaker RK, Kuehl TJ, Muir TM, Yandell PM, Pierce L, Shull, BL. Transverse cystocele repair with uterine preservation using native tissue. Int Urogynecol J (2008) 19:1275-1281.

35. Huffaker RK, Shull BL, Thomas JS. A serious complication following placement of posterior Prolift. Int Urogynecol J (2009) 20:1383-1385.

36. Huffaker RK, Livers N, Yandell PM, Shull BL, Muir TW, Kuehl TJ, Bird ET. Does Body Mass Index Impact Passing Voiding Trial After Midurethral Sling Procedures for Stress Urinary Incontinence? Female Pelvic Medicine & Reconstructive Surgery (2010) 16:6; 358.

37. Bracken JN, Tran DH, Kuehl TJ, Yandell PM, Shull BL, Transvaginal Repair of Failed Abdominal Sacral Colpopexy Utilizing Graft. Abstract Accepted at ICS/IUGA 2010, Poster presentation at ICS/IUGA 2010, Toronto, Canada, August 2010

38. Bracken JN, Reyes M, Gendron JM, Pierce LM, Runge VM, Shull BL, Kuehl TJ, Serial Magnetic Resonance Imaging of Primiparous Squirrel Monkeys Demonstrate Pelvic Floor Muscle Changes, Abstract Accepted for read by title presentation at ICS/IUGA 2010, Toronto, Canada. August 2010.

39. Bracken JN, Tran DH, Kuehl TJ, Yandell PM, Shull BL, Transvaginal Repair of Failed Abdominal Sacral Colpopexy Utilizing Graft. Poster presentation at Texas A&M University Health Science Center Collect of Medicine Student Research Forum. April 2010, College Station, TX.

PUBLICATIONS: OTHER (non-peer review)

1. Piziak V, Shull BL: Menopausal hormone replacement. Hosp Pract, 20(2):82GG, February 15, 1985.

2. Shull BL: Female urinary incontinence: Tips on office diagnosis and treatment. Consultant, 17:147, March, 1987.

3. Shull BL: Office evaluation of incontinence. Modern Med, 1989;57:84-93.

4. Shull BL: The changing face of gynecologic surgery: The "M" perspective. The Female Patient, 1990;15(Jan.):69-75.

BOOK CHAPTER

1. Shull BL: Vaginal alternative: sacrospinous colpopexy, in Surgical repair of vaginal defects (Baden WF, Walker T), JB Lippincott Co, Philadelphia Pa, 1992, pp. 175-182.

2. Shull BL: The Anatomy of Pelvic Relaxation and Stress Urinary Incontinence, in Benign Postreproductive Gynecologic Surgery edited by Marvin H. Terry Grody, M.D., McGraw-Hill, Inc., Philadelphia, PA, 1995.

3. Shull BL: Initial Evaluation and Physical Examination, in The Female Pelvic Floor -- Disorders of Function and Support, edited by Dr. Linda Brubaker and Theodore J. Saclarides, JB Lippincott Co, Philadelphia Pa, 1996.

4. Shull BL: Recurrent Protrusion of the Anterior Vaginal Wall with Vault Eversion, Paravaginal Defects, and Thin Vaginal Epithelium, in Clinical Problems, Injuries, and Complications of Gynecologic Surgery, 3rd Edition, edited by David H. Nichols and J.O.L. DeLancey, Williams and Wilkins Company, 1995.

5. Coates KW, Shull BL: Standardization of the Description of Pelvic Organ Prolapse, in Urogynecology and Urodynamics, Theory and Practice, Fourth Edition, edited by Donald R. Ostergard and Alfred E. Bent, Williams and Wilkins, 1996.

6. Shull BL: Anterior Paravaginal Defects, in TeLinde□s Operative Gynecology, Eighth Edition, edited by John A. Rock and John D. Thompson, Lippincott-Raven, 1997, pages 996-1005.

7. Bachofen CG, Shull BL: Pelvic Organ Prolapse, Enterocele and Rectocele in Urogynecology and Reconstructive Pelvic Surgery, Second Edition, edited by Mark D. Walters and Mickey Karram, accepted for publication.

8. Shull BL, Hurt G, Halaska M, Kinn A, Laycock J, Palmtag H, Reilly N, Qubieta R, Yong Yang: Physical Examination in Incontinence □ 1st International Consultation on Incontinence, edited by Paul Abrams, Saad Khoury, Alan Wein, Plymbridge Distributors Ltd, 1999, pages 333-350.

9. Shull BL: Choice of Surgery – Prolapse, in Female Pelvic Reconstructive Surgery, edited by Stuart Stanton and Philippe Zimmern.Springer-Verlag London Ltd, 2000.

10. Shull BL, Hurt G, Laycock J, Palmtag H, Yong Y, Zubieta R: Physical Examination in Incontinence – 2nd International Consultation on Incontinence, 2nd Edition 2002, edited by Paul Abrams, Linda Cardozo, Saad Khoury, and Alan Wein, Plymbridge Distributors Ltd, pages 373-388.

11. Shull BL: Choice of Surgery for Prolapse, in Female Pelvic Reconstructive Surgery, edited by Stuart Stanton and Philippe E. Zimmern. Springer – Verlag London Limited 2003, pages 368-373.

12. Shull BL, Yandell PM. Paravaginal Defect Repair, in Telinde's Operative Gynecology, 2008

Abstracts and Discussions

1. Stovall TG, Ling FW, Henry LC, Woodruff MR, (Shull BL-Official Discussant): A Randomized Trial Evaluating Leuprolide Acetate Prior to Hysterectomy for Leiomyomata (accepted for publication); Am J Obstet Gynecol, 1991; 164(6): 1420-25.

2. Shull BL, Capen CV, Riggs M, Kuehl T: Bilateral attachment of the vaginal cuff to iliococcygeus fascia: an effective method of cuff suspension. Central Association of Obstetricians and Gynecologists Annual Meeting, Chicago, October 15-17, 1992.

3. Coates KW, Galan HL, Kuehl TJ, Shull BL: The Squirrel Monkey: An Animal Model of Pelvic Relaxation. Proceedings of the 23rd Annual Meeting of the International Continence Society, Rome, Italy, 1993.

4. Discussant: Huddleston HT, Dunnihoo DR, Huddleston PM, Meyers PC. Magnetic resonance imaging of defects in DeLancey's vaginal support levels, I, II, and III. Am J Obstet Gynecol, June 1995; 172:1778-84.

5. Discussant: Paraiso MFR, Ballard LA, Walters MD, Lee JC, Mitchinson AR. Pelvic support defects and visceral and sexual function in women treated with sacrospinous ligament suspension and pelvic reconstruction. Am J Obstet Gynecol, December 1996; 175:1423-31.

6. Klouda KA, Klouda MJ, Naul LG, Kuehl TJ, Shull BL: Assessment of pelvic anatomy by magnetic resonance imaging in the adult human female, 1996 Bunkley Day Proceedings, Department of OB/GYN, Scott & White Memorial Hospital & Clinic, p 17-30.

7. Scow R, Coates KW, Shull BL, Klouda M, Piper D, Kuehl TJ: Description of the squirrel monkey pelvis using three-dimensional computer tomography. 1997 Bunkley Proceedings, Department of OB/GYN, Scott & White Memorial Hospital & Clinic, p 45-49.

8. Scow R, Coates KW, Shull BL, Klouda M, Piper D, Kuehl TJ. Three-dimensional computed tomography of the squirrel monkey pelvis. Presented at Annual Meeting of American Urogynecology Society in October 1997, Tucson, AZ.

9. Bachofen CG, Shull BL, Gayle LJ, Kuehl TJ: Enterocele repair utilizing endopelvic fascia and uterosacral cuff suspension: an illustrated text. 1997 Bunkley Proceedings, Department of OB/GYN, Scott & White Memorial Hospital & Clinic, p 57-66.

10. Shull BL, Bachofen CG, Coates KW, Kuehl, TJ: A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse using uterosacral ligaments. Oral

presentation at the 26th Scientific Meeting of the Society of Gynecologic Surgeons, New Orleans, LA, February 28-March 1, 2000.

11. Coates KW, Kuehl TJ, Bachofen CG, Shull BL. Analysis of Surgical Complications and Patient Outcomes in a Residency Training Program. 2000 Orally presented at 68th Annual Meeting of the Central Association of Obstetricians and Gynecologists.

12. Vineyard DD, Kuehl TJ, Coates, KW, Shull BL: A Comparison of Preoperative, Intra-operative and Post-surgical Evaluations in Patients Undergoing Site-Specific Surgery for Correction of Pelvic Organ Prolapse. (1) Error! Bookmark not defined. Proceedings, 42nd T. F. Bunkley Lectureship/11th Annual Resident Research Day, Temple, Mar 23, 2001 (Winner, Best Presentation) (2) Presented orally at 9th Annual Texas Resident Research Day/72nd Annual Texas Association OB/GYN-Texas Section ACOG Annual Meeting, Apr 6, 2001, Austin, TX

13. Sulak PJ, Ortiz M, Kuehl TJ, Shull BL. Acceptance of Altering the standard 21/7 Day Oral Contraception Regimen 2001. Accepted for presentation and published as abstract. Central Association of OB/GYN Annual Meeting scheduled for October 10-13, 2001, in San Francisco, CA, cancelled due to "9-11".

14. Vineyard DD, Kuehl TJ, Coates KW, Shull BL. A Comparison of Preoperative and Intraoperative Evaluation in Patients Undergoing Site-Specific Surgery for Correction of Pelvic Organ Prolapse. Accepted for presentation and published as abstract. Central Association of OB/GYN Annual Meeting scheduled for October 10-13, 2001, in San Francisco, CA, cancelled due to "9-11".

15. Kramer LA, Gendron JM, Pierce LM, Runge VM, Shull BL Kuehl TJ: Magnetic Resonance Imaging of the Levator Ani in the Squirrel Monkey: A Comparison of Muscle Volume Between a Cohort With Pelvic Organ Prolapse and Matched Normals. Oral paper presentation at the American Urogynecologic Society 26th Annual Scientific Meeting, September 15-17, 2005, Atlanta, Georgia.

16. Stratford RR, Baumann SS, Jamroz RC, Kuehl TJ, Shull BL, Pierce LM: Poster 14: Histology and Differential mRNA Expression in Vaginal Connective Tissue of Women With Pelvic Relaxation. The American Urogynecologic Society 26th Annual Scientific Meeting, September 15-17, 2005, Atlanta, Georgia.

17. Stratford RR, Runge V, Gendron J, Pierce LM, Shull BL, Kuehl TJ. A comparison of levator ani muscle volumes in nulliparous and multiparous women using 3-dimensional magnetic resonance imaging. Oral paper presentation at the Central Association of Obstetricians and Gynecologists Scientific Meeting, October 2005, Scottsdale, AZ.

18. Stratford RR, Kuehl TJ, Coates KW, Thor KB, Shull BL and Pierce LM. (2005). Evaluation of the squirrel monkey model of pelvic organ prolapse: anatomical and histological comparisons of the pelvic floor between women and squirrel monkeys. International Urogynecological Association 2005 Scientific Meeting, August 9-12, Copenhagen, Denmark. Awarded Best Oral Poster Presentation.

19. Stratford RR, Baumann SS, Jamroz RC, Kuehl TJ, Shull BL, Pierce LM. Apoptosis and differential mRNA expression in vaginal connective tissue of women with pelvic relaxation. Oral paper presentation at the Central Association of Obstetricians and Gynecologists Scientific Meeting, October 2005, Scottsdale, AZ.

20. Kramer LA, Gendron JM, Pierce LM, Runge VM, Shull BL, Kuehl TJ. Magnetic resonance imaging of the levator ani in the squirrel monkey: a comparison of muscle volume between a cohort with pelvic organ prolapse and matched normals. AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY 2006; 194:1467-71.

AUDIO/VIDEO PRODUCTIONS

1. Paravaginal Defect Repair for Stress Urinary Incontinence (presented at Annual ACOG Meeting, Boston, Massachusetts, April, 1988) Accepted for inclusion in the Motion Picture Library, American College of Surgeons, 1991.

2. Using Laparoscopic Photography to Teach Retropubic Space Anatomy and Surgery (presented at Annual APGO/CREOG meeting, New Orleans, March, 1989

3. Shull BL, Baker DB, Masterson BJ: Discussion. Audio Digest: General Surgery, Pelvic and Vaginal Surgery. 37(2), January 24, 1990.

4. Shull BL: Office workup of stress urinary incontinence. Audio Digest: General Surgery, 37(6), March 13, 1990

5. Shull BL: Clinical Evaluation of Vaginal Defects. Audio Digest: Obstetrics and Gynecology, "Pelvic and Vaginal Surgery", Vol. 38, No. 21, November 5, 1991

6. Shull BL: Operative Management of Vaginal Prolapse. Audio Digest: Obstetrics and Gynecology, "Pelvic and Vaginal Surgery", Vol. 38, No. 21, November 5, 1991

7. Shull BL: Vaginal Paravaginal Repair. Video produced October 1992.

8. Coates KW, Fanning P, Shull BL: Enterocele. Video produced June 1995.

9. Shull BL: Vaginal Paravaginal Repair. Medical Video Productions, The Video Reference of Vaginal Surgery, August 1996.

10. Shull BL, Guest Lecturer:Audio-Digest: Obstetrics and Gynecology, Panel Discussion on Advanced Gynecologic Surgery, Part 2", Vol. 44, No.24, December 15,1997.

EXHIBITS

1. "Vaginal Pessaries and Their Use in Pelvic Relaxation" (Sulak PJ and Shull BL) presented at 38th Annual Clinical Meeting, American College of OB/GYN, San Francisco, 1990.

CME ACTIVITES - LECTURES AND PRESENTATIONS AND CME MEETINGS ATTENDED/COMMITTEE/SOCIETY MEETINGS:

2011

Dec 1-3: Guest faculty, 21st Annual Postgraduate Course in Advanced Gynecologic Surgery in San Francisco, CA. Presenting: "Uterosacral Ligament Suspension of the Vaginal Apex", "Surgical Management of Anterior Wall Support", "The Role of Uterine Preservation in Reconstructive Surgery" and "Is there a cure for pelvic floor dysfunction?".

Nov 28: Guest speaker: Melbourne Australia, RANZCOG Plenary Lecture: "Is There a Surgical Cure for Disorders of the Pelvic Floor" and "The Place of Physical Examination in Planning Reconstructive Surgery".

Nov 25: Guest speaker: Mercy Hospital, Melbourne Australia, live surgery workshop. Presenting: "Apical Support, the Cornerstone to Successful Reconstructive Surgery".

Oct 24: Faculty, Advanced Pelvic Floor Surgery course in Salado, Texas. Presenting: "Overview of Prolapse" and "Demo-Uterosacral Ligament Procedure" and present 2 cases of vaginal reconstructive surgery using the principles discussed in class.

Oct 20-21: Guest speaker, the ACOG 2011 District IV annual meeting in Naples, FL. Presenting: "Valuable Lessons I Learned from Dr. Cullen Richardson's Observational Skills".

Sept 14-16: Attended the AUGS 32nd Annual Scientific meeting in Providence RI.

Aug 11-12: Guest speaker, 2011 Annual meeting of the Ob/Gyn Society of South Carolina in Charleston, SC.

July 20: Guest speaker: Grand Rounds, Department of Obstetrics and Gynecology at University of Texas Southwestern Medical School presenting: "Recent FDA Warning Re: Dangers of Mesh".

May 15-17: Program Director for the (S&W/TAMU sponsored) Advanced Pelvic Floor Surgery Course in Salado, TX

May 13: Attended the (S&W/TAMU sponsored) 3rd Annual F. Lurry Leavelle Lectureship in conjunction with the 52nd Annual T.F. Bunkley Lectureship and 24th Annual Baker Alumni Society meeting in Temple, Texas.

April 11-14 Attended the 37th Annual SGS Scientific meeting in San Antonio, TX

Jan 24-28 Teaches gynecologic surgery in Chennai, India during a mission trip.

2010

Dec 2-4 Guest Speaker at the 20th Annual Postgraduate Course in Advanced Gynecologic

Surgery in Chicago, IL. Presenting "Planning Surgical Strategies: The Physical Examination", "Anterior Wall Support", "The Role of Uterine Preservation in Reconstructive Surgery", and "Is there a cure for pelvic floor dysfunction?".

Oct 25-26 Faculty for the Advanced Pelvic Floor Surgery course in Salado, Texas.

Oct 4-5 Attended the IUGA Symposium in Tel Aviv, Israel.

Sept 29-Oct 1 Attended the AUGS 31st Annual Scientific meeting in Long Beach, CA.

Aug 21-29 Attended the 40th Annual IUGA meeting in Toronto, Canada.

May 7 Attended the (S&W/TAMU sponsored) 51st Annual T.F. Bunkley Lectureship and 23rd Annual Resident Research Day, and 19th Annual Baker Alumni Society meeting in Temple, Texas. May 7, 2010

May 2-4: Faculty for the (S&W/TAMU sponsored) Advanced Pelvic Floor Surgery with Hands-On Cadaver Lab and Live Surgery course in Salado, Texas.

Apr 10-14 Attended the 36th Annual SGS meeting at the JW Marriot Starr Pass Resort & Spa, Tucson, Arizona.

Apr 14-18 Attends the 81st Annual Joint meeting of the Texas Association OB/GYN and District XI ACOG and 18th Annual Texas Junior Fellow Resident Research Forum at Moody Gardens Hotel, Galveston, Texas.

Mar 13-20 Attends a missionary trip to Guatemala.

Feb 19 Faculty for the Update in Urogynecology and Female Urology at the Houston Omni Hotel in Houston, Texas. Presenting "Vaginal Approach to Prolapse Repair" and "Planning Surgeries based on Physical Findings".

2009

Dec 2-6 Faculty for the 19th Annual SGS Postgraduate Course in Advanced Gynecologic Surgery meeting in Chicago, IL. Presenting: "Contemporary Concepts in the Evaluation and Management of Pelvic Organ Prolapse", "Is there a cure for pelvic floor dysfunction?", "Planning Surgical Strategies: The Physical Examination" and "The Rose of Uterine Preservation in Reconstructive Surgery".

Oct 16-18 Guest Speaker for the 2009 Annual District Meeting in Asheville, NC. Presenting "Dr. A. Cullen Richardson – His Influence on 21st Century Reconstructive Surgery and Surgeons".

Oct 11-13 Program Director for the S&W/TAMU Sponsored Advanced Pelvic Floor Surgery Conference in Salado, Texas.

Sept 23-27 Attended the AUGS 30th Annual Scientific meeting in Hollywood, FL.

Aug 20-22	Visiting Professor for Grand Rounds at the University of Missouri, St. Louis, MO
June 14-20	Attended the IUGA 2009 meeting in Como, Italy.
May 10-12	Guest Faculty for the (S&W/TAMU sponsored) Advanced Pelvic Floor Surgery Course in Salado, Texas. Presenting "Overview of Prolapse" and "Demo-Uterosaral Ligament Procedure".
Apr 20-24	Invited Guest Professor to the Ireland Continence Society.
Apr 10-11	Attended the (S/W - TAMU sponsored) Inaugural F. Lurry Leavelle Lectureship in conjunction with the 50th Annual T.F. Bunkley Lectureship and 22nd Annual Resident Research Day, and 18th Annual Baker Alumni Society Meeting in Temple, Texas
Apr 9-11	Invited Guest Speaker for the Continence Society of the United Kingdom.
Apr 2-4	Attended the 80th Annual Joint Meeting of the Texas Association of Ob/Gyn and District XI ACOG and the 17th Annual Texas Junior Fellow Resident Research Forum, Austin, Texas, April 2-5, 2009
Mar 28-Apr 1	Attended the 35th Annual SGS meeting in New Orleans, LA
Jan 26-30	Attends the "Faith in Practice" surgical mission to Guatemala.

2008

Nov 16-18	Program Director for the Advanced Pelvic Floor Surgery course in Salado, TX
Oct 2-4	Faculty for the 18th Annual Postgraduate Course in Advanced Gynecologic Surgery at Lake Buena Vista, FL, presenting "Planning Surgical Strategies: The Physical Examination", "The Role of Uterine Preservation in Pelvic Reconstructive Surgery", "Contemporary Concepts in the Evaluation & Management of Pelvic Organ Prolapse", and "Is There a Cure for Pelvic Floor Dysfunction?"
Sept 19-20	Faculty at the 1st Annual ACOG District XI, Section 1 (West Texas) meeting in Odessa, Texas speaking on "Physical Findings in Pelvic Organ Prolapse Patients" and "Uterine Preservation in Surgery for Pelvic Organ Prolapse."
June 2-6	Attended the Toyota Business Techniques training meeting in Belton, TX.
May 5-6	Guest Speaker for the annual ACOG meeting in New Orleans, LA
Apr 27-29	Program Director for the Advanced Pelvic Surgery Course in Salado, TX
Apr 24-25	Attended an educational meeting at Texas Tech at Amarillo, TX
Apr 18	Attended the 49th Annual TF Bunkley Lectureship and 21st Annual Resident Research Day at Scott & White, Temple, Texas, Apr 18, 2008
Apr 13-16	Faculty for the 34th Annual SGS meeting in Savannah, GA
Mar 27-28	Attended the 79th Annual TAOG meeting in Ft. Worth, Texas.

2007

Dec 6-7	Faculty for the 17th Annual Postgraduate Course in Advanced Gynecologic Surgery in

	Chicago, Illinois, presenting "Contemporary Concepts in the Evaluation and Management of Pelvic Organ Prolapse", "Is There a Cure for Pelvic Floor Dysfunction", "Planning Surgical Strategies: The Physical Examination", and "The Role of Uterine Preservation in Reconstructive Surgery".
Nov 29-12/1:	Attended the Pelvic and Vaginal Surgery Conference in San Antonio, Texas.
Oct 14-16	Program Director for the Advanced Pelvic Floor Surgery course in Salado, TX
Jul 17-20	Visiting Professor in India.
Jun 11-15	Attended the IUGA 32nd Annual meeting in Cancun, Mexico.
Jun 7-9	Dr. Shull is speaker for the Northwestern Medical School, Advances in Urogynecology and Reconstructive Pelvic Surgery conference at the Hotel InterContinental in Chicago, Illinois presenting "No Absolutely Not", "Estogen Effects in the Lower Urinary Tract", "Paravaginal repairs, what is the state of the art", and "Surgical anatomy of the pelvis".
Apr30-May 1	Program Director for the Advanced Pelvic Floor Surgery course in Salado, Texas.
April 26-27	Gynecology Chair at the 6th Annual International Symposium on Female Urology & Urogynecology in Las Vegas, NV.
April 11-15	Annual Clinical meeting of the Thirty-Third Annual SGS Meeting in Orlando, Florida.
Mar 26-30	Visiting Professor and Surgeon guest professor at Ospedale Gemelli Rome, Italy
Mar 10-12	Visiting Professor, Cleveland Clinic at Fort Lauderdale, FL
Mar 2	Visiting Professor for resident research day at Texas Tech.

2006:

Dec 1	Program Director for the 20th Annual Update in Pelvic and Vaginal Surgery in San Antonio, Texas
Nov 14-15	Visiting Professor at the Chinese University of Hong Kong for the Vaginal Reconstructive Surgery Workshop.
Oct 27	Director, Lonnie Burnett video symposium, ACOG District VII meeting in West Virginia.
Oct 18-22	Attended the 27th Annual AUGS Scientific Meeting in Palm Springs, CA
Oct 15-17	Director for the Advanced Pelvic Surgery course in Salado, Texas.
Sept 12-13	Visiting Professor, 2nd Annual Paul B. Underwood Lecture at the University of Virginia, VA.
June 14-16	Visiting surgeon at the Urogynecologic Reconstructive Surgical Society of India, Chennais, India
June 7-9	Visiting Professor at the British Society of Urogynecology Royal College of Ob Gyn, London and visiting surgeon, Department of Gynaecology, Plymouth, England
Apr 23-25	Director for the Advanced Pelvic Floor Surgery meeting in Salado, Texas presenting: "Overview of Prolapse" and a demo on "Uterosacral ligament procedure".
Apr 7-9	Guest speaker at the Fifth Annual International Seminar on Female Urology and Urogynecology, Philadelphia, PA presenting: "Evaluation of Pelvic Organ Prolapse", "Appliances & Pessaries", "Surgical Concepts of Prolapse Repair", and "How to do a good pelvic exam".
Apr 1-5	Attended the 32nd Annual SGS meeting in Tucson, AZ
Feb 24-25	Guest Speaker for the Texas Clinical Symposium on Female Pelvic Surgery in Houston, Texas presenting "Management and Prevention of Complications of Pelvic Reconstructive Surgery" and "Is There a Surgical Cure for Pelvic Floor Dysfunction?".
Feb 16-18	Guest Speaker at the ACOG Postgraduate course on Advanced Pelvic Surgery in St. James, Jamaica, presenting "Current Concepts in Disorders of the Pelvic Floor", "Planning Surgery for Pelvic Organ Prolapse", "Global POP – Vaginal Approach", and "Surgical Complications of Treatment for Urinary Incontinence".
Jan 8-15:	Board Examiner for ABOG in Dallas, Texas.

2005:

Dec 28-31	Visiting Professor and surgeon at Gortsabo Ghandi Hospital, Chennai, India.
Dec 2-3:	Faculty at the 19th Annual Update in Pelvic and Vaginal Surgery in San Antonio, Texas

presenting: "Current concepts in disorders of the pelvic floor" and "Evaluation of women with pelvic organ prolapse".

Nov 10-12: Guest Speaker for the National Association for Continence (NAFC) in Durham, NC, presenting: "A Physiology Refresher – The Lower Urinary Tract and the Pelvic Floor".

Oct 23-25: Program Director and Faculty for the Advanced Pelvic Floor Surgery meeting in Salado, Texas presenting: "Management of Enterocele and Apical Prolapse Vaginally" and "Complications of Pelvic Surgery".

Sept 12-16: Guest Speaker at the 26th Annual AUGS Scientific meeting in Atlanta, Georgia presenting: "Anterior Repair and Paravaginal Repair", "Global Pelvic Organ Prolapse – Vaginal Approaches", and "Is There a Surgical Cure for Pelvic Floor Dysfunction?".

Aug 29-30: Keynote speaker for Research Retreat for the International Continence Society meeting on Anatomic Concepts of Genital Prolapse Etiology: Relation to Current Strategies of Prolapse Surgery in Montreal, Canada presenting: "Anatomic Cuff Fixation", "Diagnosis and Pathophysiology of Prolapse", and "Enterocele Repair with Vault Prolapse".

Aug 7-13: Keynote speaker for the 30th Annual International Urogynecological Association meeting on "Urogynecology: Where are we and were should we be?" in Copenhagen, Denmark.

May 7-11: Guest Speaker for the 53rd Annual Clinical Meeting of ACOG, 120 Course Complex Gynecologic Surgery: Preventing and Managing Complications in San Francisco, CA, presenting "Hysteroscopy Complications", "Complications of Surgery for Urinary Incontinence", "Management of Complications of Pelvic Reconstructive Surgery", and "Planning Reconstructive Surgery".

Apr 17-18: Faculty for the Advanced Pelvic Floor Surgery in Salado, Texas presenting "Management of Enterocele and Apical Prolapse Vaginally" and "Complications of Pelvic Surgery".

Apr 7-9 Program Faculty for the 76th Annual meeting of ACOG Texas Section and the Texas Association of Obstetrics and Gynecologists in Austin, Texas, presenting: "Contemporary Concepts in Pelvic Organ Prolapse".

Apr 2-6 Attends the 31st Scientific meeting of the Society of Gynecologic Surgeons at Rancho Mirage, California.

Mar 31–Apr 2 Guest Speaker at the 4th Annual International Seminar on Female Urology and Urogynecology in Las Vegas, Nevada presenting "Evaluation of Pelvic Organ Prolapse", "Defecatory Dysfunction", "How to do a good pelvic exam – video", "Retropubic Operations", "Is there a role for mesh augmented vaginal prolapse repairs?", and "Ureterosacral suspension".

Feb 17-19: Guest Speaker for the ACOG Postgraduate Course on Advance Pelvic Surgery in St. Thomas, V.I., presenting "Rectocele", "Complications of Incontinence Surgery", and "Retropubic Suspension and Urethral Slings".

Jan 26-27: Visiting Professor for Grand Rounds at Duke University in North Carolina, presenting "Is there a surgical cure for disorders of the pelvic floor?"

Jan 9-14: Board Examiner for ABOG in Dallas, Texas.

2004:

Dec 3-4: Program Director at the Eighteenth Annual Update in Pelvic and Vaginal Surgery in San Antonio, Texas.

Oct 24-26 Course Director for Advanced Pelvic Floor Surgery in Salado, TX.

Oct 23 Guest Speaker for Advances in Genitourinary Health in Chicago, IL presenting "Pelvic Organ Prolapse: Diagnosis, Conservative, and Obliterative Therapies".

Oct 16 Guest Speaker at the Southwest Ob-Gyn Seminar in San Antonio presenting "Surgical Management of Uterovaginal Prolapse" and "Contemporary Concepts in Disorders of the Pelvic Floor".

Oct 12 Guest Speaker for the Central Travel Club (CAOG) meeting presenting "Contemporary Concepts in Disorders of the Pelvic Floor" in Washington, DC

Oct 9-11	District VII ACOG meeting in Washington, DC. Presenting the Lonnie Burnett video seminar on Pelvic Surgery.
Sep 30-Oct 2	Guest Speaker at the SGS – 14th Annual Postgraduate Course in Advanced Pelvic Surgery in Chicago, IL. Presented: "Contemporary Concepts in Disorders of the Pelvic Floor", "Burch vs. Paravaginal Repair", "Complications of Incontinence Surgery", and "Is There a Surgical Cure for Disorders of the Pelvic Floor?".
Jun 4	Faculty, 2004 Resident Research Day, University of Pittsburgh School of Medicine, Magee Women's Hospital, Pittsburgh, Pennsylvania
Apr 16	45th Annual Bunkley Day Lectureship & 17th Annual Resident Research Day, Scott & White Memorial Hospital, Temple, Texas
Apr 26	Faculty, Advanced Pelvic Floor Surgery, Salado, Texas
Mar 23	Speaker, Cadaver Course, Dallas, Texas
Jan 28-30	Faculty, ACOG Meeting, San Jose, Costa Rica
Jan 12-16	ABOG Board Examiner, Dallas, Texas

2003:

Dec 3-4	Faculty, Pelvic & Vaginal Surgery course, San Antonio, Texas
Oct 1	Attended Annual CAOG meeting, California,
Oct 16-20	Attended District VII ACOG annual meeting, Ashville, North Carolina
Oct 27-28	Faculty, Advanced Pelvic Floor Surgery, Salado, Texas
Sept 11-12	Attended the 7th Annual American Urogynecologic Society meeting, Florida.
Jun 18-20	Guest Faculty for Scott & White Course, The Adult , Male and Female Issues, "Examination of the Patient with Prolapse", "surgical Management of Urinary Incontinence; What's IN? What's OUT?", "Pharmacologic Management of Urinary Incontinence", "Is There Surgical Cure for Disorders of the Pelvic Floor: What Can Your Patient Expect?", South Padre Island, Texas
May 9	Attended 44th Annual T.F. Bunkley Lectureship & 16th Annual Resident Research Day, Scott & White Hospital, Temple, Texas
Apr 4	Attended the 74th Annual Texas Association of Obstetricians & Gynecologists, Galveston, Texas.
Mar 5-7	Attended the Annual Society of Gynecologic Surgeons meeting, Anaheim, CA
Mar 27-29	Speaker–ACOG freestanding postgraduate course entitled "Advanced Surgical approaches to Incontinence & Prolapse". Presenting "Burch Procedure and Paravaginal Repair for Treatment of Stress Urinary Incontinence", "Complications of Incontinence Surgery", "Obliterative Procedures: Total Colpocliesis and LeFort", and "Is There a Cure for Pelvic Floor Dysfunction?"
Jan 11-18	ABOG Board Examiner, Dallas, Texas

2002:

Dec 6	Faculty, Pelvic and Vaginal Surgery Course, San Antonio, Texas
Nov 7-9	Faculty - 12th Annual Postgraduate Course in Advanced Gynecologic Surgery. Presented Is There a cure for Pelvic Floor Dysfunction, Contemporary Concepts in the Evaluation and Management of Pelvic Organ Prolapse, Retropubic Anatomy and Repairs for Urinary Incontinence and Complications of Incontinence Surgery, New York, New York
Oct 5	Speaker for a Women's Forum: Lifelong Pelvic & Bladder Health at the National Association for Continence meeting in Houston presenting "Risk factors for development of urinary incontinence".
Oct 12	Faculty at the ACOG – District VII meeting in New Orleans directing the Lonnie Burnett video session.
Oct 13-15	Course Director for the Advanced Pelvic Surgery course, Salado, Texas
Oct 17-19	Moderator of Panel on Finance in Urogynecology and Past-President's Committee at the AUGS – 23rd Annual scientific meeting, San Francisco, California

Oct 25-27	Attend the Central Travel Club meeting in Las Vegas, Nevada
Oct 28	Attends the Central Association of Obstetricians-Gynecologist Annual Meeting in Las Vegas, Nevada
Sept 27-28	Faculty -- Washington Section/ACOG and Seattle Gynecology Society 45th Annual Fall Assembly in Seattle, Washington presenting "Is there a cure for pelvic floor dysfunction", "Burch – paravaginal repair for treatment of stress urinary incontinence", and "The use of native tissue"
Sept 17-20	Visiting Professor and Surgeon 6th Annual German Urogynecological Meeting, Berlin, Germany
Aug 3-4	Guest Speaker - 4th Annual Female Incontinence and Pelvic Organ Prolapse/Practical Urogynecologic Anatomy with Cadaver Dissection meeting. Presented Is There a Surgical Cure for Pelvic Floor Dysfunction, Vaginal Surgery Pearls, Vaginal Approaches to Reconstructive Surgery and Anterior Vaginal Wall and Retropubic Procedures, University of Texas Southwestern Medical Center, Dallas, Texas
Jan 6-11	Oral examiner for ABOG, Dallas, Texas

2001:

Feb 2-4	Faculty, The American Association of Gynecologic Laparoscopists Postgraduate Course on "Urogynecology & Reconstructive Pelvic Surgery: What is the Role of Laparoscopy?", Miami Beach, Florida. "Preoperative Evaluation of the Lower Urinary Tract in Women With Advanced Pelvic Organ Prolapse", "Defecatory Dysfunction, Rectocele and Anal Incontinence: What Every Gynecologist Should Know", "Anterior Vaginal Wall Defects and Stress Incontinence: How Are They Best Managed?", "Contemporary Use of Pessaries", and "Vaginal Vault Prolapse and Enterocele – Vaginal Approaches".
Feb 23	Guest Faculty, The Thomas E. Elkins Memorial Lecture, Dept. of OB/GYN, Johns Hopkins School of Medicine, Baltimore, Maryland, "Ethics, Eugenics, and Pelvic Prolapse"
Feb 24	Guest Faculty, The 18th Annual Houston Everett Memorial Postgraduate Course in Urogynecology, Johns Hopkins University School of Medicine, Baltimore, Maryland ,"Defect Approach to Anterior Vaginal Reconstruction"
Feb 25-Mar 3	Guest Faculty, 42nd Annual Ob/Gyn Update postgraduate course presented by the University of Utah School of Medicine in Park City, Utah, "Contemporary Concepts in the Evaluation and Management of Pelvic Organ Prolapse", "The Use of Native Tissue in the Vaginal Approach to Prolapse", and "Complications of Surgery for Urinary Incontinence".
Mar 3-7	President Elect and panel member, Society of Gynecologic Surgeons Annual Meeting, Orlando, Florida, " Complications of Pelvic Surgery"
Mar 9	Visiting Professor, Lehigh Valley Hospital, Dept of OB/GYN, Allentown, Pennsylvania, "Management of Vaginal Vault Prolapse."
Mar 23-24	42nd Annual T. F. Bunkley Lectureship/14th Annual Resident Research Day/11th Annual Meeting of the Baker Society, Temple, Texas
Mar 29-31	Faculty/Host for the Central Travel Club Ob/Gyn Meeting, Salado, Texas: live demonstration of surgical techniques in pelvic reconstructive surgery
Apr 4-6	Attends the 72nd Annual TAOG/Texas Section ACOG Meeting, Austin, Texas.
Apr 22-24	Program Director, Advanced Pelvic Floor Surgery Course (S&W/TAMU) Salado, Texas: Live vaginal reconstructive surgery -- two cases. Lectures: "Open procedures for urinary incontinence" and "Vaginal repair for vaginal prolapse"
Jul 2-5	Consultant to the World Health Organization, Paris, France.
Sept 21	Guest Speaker, Oklahoma Section ACOG Meeting: "Management of the Posterior Compartment"
Sept 22-26	Distrit VII ACOG Annual Meeting, Tulsa, OK: conducts the Lonnie S. Burnett Video Seminar

Sept 27	GuestSpeaker, Austrian Society for Urogynecology and Reconstructive Surgery, Vienna, Austria, "Is There a Surgical Cure for Pelvic Floor Dysfunction?"
Oct 11-12	Faculty, 11th Annual Postgraduate Course in Advanced Pelvic Surgery (Society of Gynecologic Surgeons), New York, NY: "Management of Mixed Incontinence", "Current Concepts in the Management of Pelvic Organ Prolapse", "Complications of Incontinence Surgery", and "Retropubic Space Surgery" and Elected to President, SGS, 2001-2002
Oct 21-23	Course Director and Faculty for an Advanced Pelvic Floor Surgery Course, Salado, Texas (S&W/TAMU sponsored)
Ot 25-27	Annual American Urogynecologic Society (AUGS) Meeting, Chicago, Illinois: Presents the J. Marion Sims Lecture, "Is there a Surgical Cure for Pelvic Floor Dysfunction?"
Nov 9-10	Program Director and Faculty, 15th Annual S&W/TAMU Update in Pelvic and Vaginal Surgery Course, San Antonio: "How to do Various Retropubic Urethropexies: Marshall-Marchetti-Krantz", "Compartmentalization of Pelvic Floor Defects", and "Management of Posterior Compartment Defects".
Dec 3-7	The International Urogynecologic Association Meeting, Sydney, Australia, Presenting the Keynote Address on "The Use of Native Tissue in Pelvic Reconstructive Surgery" and performed a workshop on Vaginal Surgery for Uterovaginal Prolapse and performed live surgery demonstrations.

2000:

Guest Speaker, American Urological Association Postgraduate Course on Female Urology/Urogynecology: A Meeting of the Minds, New York City, New York, 1/16-18/00: "Retropubic Prolapse - Diagnosis & Pathophysiology", "Pelvic Organ Prolapse - Planning a Surgical Approach", "Surgical Treatment of Uterine Prolapse, including Hysterectomy and Prophylaxis Against Prolapse", Surgical Treatment of Anterior Compartment Defect: Vaginal Approach", "Surgical Treatment of Posterior Compartment Defects", "Surgical Treatment of Superior (Apical) Defects: Vaginal Approach and "Surgical Treatment of Superior (Apical) Defects: Abdominal Approach"

Faculty for "Update in Gynecologic Urology In St Thomas", (Northwestern University/ Cleveland Clinic sponsored), St. Thomas, Virgin Islands, 2/10-12/00: "Effects of Estrogen on the Lower Urogenital Tract", "Prolapse Videos", "Anterior Vaginal Wall Prolapse Including Paravaginal Repair", "Abdominal Repair of Vaginal Vault Prolapse (Open and Laparoscopic)", "How I Approach Vaginal Vault Prolapse from Below", and "What I do Surgically for My Patients and Why"

Visiting Faculty, 26th Annual Vail Obstetrics and Gynecology Conference (Department of Ob/Gyn, University of Colorado School of Medicine) Vail, Colorado, 2/20-25/00: "How I do a Vaginal Hysterectomy", "How I Repair Vaginal Apical Prolapse", "Management of Urinary Incontinence" and "Pelvic Reconstruction"

Guest Faculty for the 17th Annual Houston Everett Memorial Course in Urgynecoogy, Johns Hopkins University School of Medicine, Baltimore, Maryland, 2/26/00: "Complications of Incontinence and Pelvic Reconstructive Surgery", "Defect Approach to Anterior Reconstructive Surgery", "Vaginal and Paravaginal Repair", and "Vault Prolapse - Texas Technique and Experience"

Annual Meeting of the Society of Gynecologic Surgeons, New Orleans, Louisiana, 2/28-3/1/00: "A Transvaginal Approach to Repair of Apical and Other Associate Sites of Pelvic Organ Prolapse Using Uteroscacral Ligaments" and serves as Discussant for a paper presentation, "Abnormal Spinal Curvature and its Relationship to Pelvic Organ Prolapse", and roundtable discussion on "Standardization of Terminology for Pelvic Organ Prolapse, Urinary Incontinence, and Fecal Incontinence"

Faculty for "Advances in Urogynecology & Pelvic Organ Prolapse for the New Millenium", (sponsored by Univ of Texas HSC, Houston), Houston, Texas, 3/3-4/00: "Anatomy & Surgical Correction of Paravaginal Defects" and "Update on Surgical Management of Recurrent Prolapse".

41st Annual T. F. Bunkley Lectureship/13th Annual Resident Research Day/10th Annual Baker Alumni Society Meeting, (S&W/TAMU), Temple, 3/24-25/00

Guest Speaker for the University of Stellenbosch Faculty of Medicine, Department of Ob/Gyn, Capetown, South Africa, 3/30-31/00, presenting a day seminar on "Practical Management of Genital Prolapse", including "Contemporary Concepts in the Pathophysiology and Management of Pelvic Organ Prolapse".

71st Annual TAOG/Texas Section ACOG Meeting, San Antonio, Texas, 4/6-8/00

Guest Speaker, Annual Consultants Review at the Royal College of Obstetricians and Gynecologists, Warwick, England, 5/22/00: "Management of the posterior compartment" and "Surgical management of urinary incontinence"

Invited lecturer: Nordic Congress of Obstetrics and Gynecology. Oslo, Norway, 6/3-6/00: "Genital prolapse: The way we do it" and "Functional anatomy of urogenital prolapse".

Guest Speaker for the Florida Obstetrical and Gynecological Society, Naples, Florida., 7/27-30/00: "Enterocele", "The underlying concepts of pelvic floor disorders", and "How to pick an operation for pelvic organ prolapse".

Speaker, "2nd Annual Update in Female Incontinence and Pelvic Organ Prolapse" Symposium at The University of Texas Southwestern Medical Center, Dallas, Texas, 8/5/00: "Site-specific approach to pelvic organ prolapse" and "Office evaluation of pelvic organ prolapse/urinary incontinence".

Served as Panel Member at the Annual FIGO Meeting, Washington, D.C. Subject: Use of Synthetic Graphs in GYN Surgery, 9/6/00

Central Travel Club OB/GYN Meeting, Green Bay, Wisconsin, 9/9-10/00

Speaker, District VII Annual District VII ACOG Meeting, St. Louis, Missouri, 9/30-10/4/00: Presented the Lonnie Burnett Video Seminar on Pelvic Organ Prolapse

Speaker, 10th Annual Postgraduate Course in Advance Gynecologic Surgery, New York, New York, 10/5-7/00: "Retropubic anatomy and repairs for urinary incontinence" and "Laparoscopic correction of incontinence and prolapse".

Annual Meeting of the American Urogynecology Society in Charleston, South Carolina, 10/26-29/00

Discussant, Central Association of Ob/Gyn Annual Meeting, Chicago, Illinois, 10/19-20/00. "Prospective, Randomized Trial of Polyglactin 910 Mesh to Prevent Recurrence of Cystocele and Rectocele".

Invited speaker for the Italian Urodynamic Society, Bologna, Italy, 10/22-26/00: Live surgery for pelvic organ prolapse, and "Contemporary concepts in the evaluation and management of pelvic organ prolapse".

Program Director and Faculty for a S&W/TAMU sponsored "Advanced Pelvic Floor Surgery" course (S&W/TAMU), Salado, Texas, 11/5-7/00: "Anatomy for the Pelvic Reconstructive Surgeon: Clinical Applications", "Testing Bladder Function", "Rectocle-Video Presentation", "Pathophysiology of Enterocele and Vaginal Prolapse", "Prolapse Repair: A Gynecologists' Approach", and conducts live surgery cases.

Program Director, 13th Annual W.F. Baden Lectureship in Gynecology, Scott & White, 11/30/00

Program Director, 14th Annual Update in Pelvic and Vaginal Surgery, San Antonio, Texas, 12/1-2/00: Presented "Tension Free Vaginal Tape", "How to manage post operative obstruction voiding", "Compartmentalization of pelvic floor defects", and "Anterior compartment defects".

1999:

Guest Speaker and Visiting Surgeon, Tripler Army Base, Honolulu, Hawaii., 1/18-22/99

25th Annual Society of Gynecology Surgeons meeting, San Diego, California, 2/18-19/99

Committee Member to Rewrite Test Booklet, Gynecologic surgery and Oncology. American College of Obstetricians and Gynecologist, Prolog, Washington, DC, 3/5/99

Chicago Gynecologic Society, Guest Speaker "The vaginal approach to pelvic prolapse". Grand Rounds, Guest Speaker, Loyola University School of Medicine. Grand Rounds, Illinois Lutheran Medical Center, 3/17/99

Faculty speaker for the Stanley F. Rogers Symposium, Houston, Texas., 3/26-27, 99

Speaker, University of Connecticut Postgraduate Course, Hartford, Connecticut, 4/6-7/99

Executive Committee member and Faculty Speaker, 70th Annual Texas Association of Obstetrics and Gynecologist, Houston, Texas, 4/16-17/99: Selecting the Proper Operation for Urinary Incontinence and Enterocele,

Visiting Professor, University of Virginia, "Contemporary Concepts in Pelvic Organ Prolapse: Evaluation and Surgery", Charlottesville, Virginia, 4/23/99

S&W/TAMU Advanced Pelvic Surgery Course, (Program Director), Salado, Texas, 5/3/99: "Anatomy for the Gynecologic Surgeon – Clinical Applications", "Pathophysiology of Enterocele and Prolapse of the Cuff", "Vaginal Repair", "Rectocele", "Overview of Surgery for Urinary Incontinence" and Two Cases of Vaginal Reconstructive Surgery Using the Principles Discussed

Guest Speaker, Alabama Section, American College of Obstetricians and Gynecologist, Birmingham, Alabama, 5/6-7/99: "Enterocele Medical Management during incontinence"

Grand Rounds Speaker and Faculty for the Resident Education Day, Department of OB/GYN, University of South Carolina, Greenville, South Carolina, May 13-16/99: "Enterocele and Complications of Urinary Incontinence Surgery", "Selecting the Proper Operation for Urinary Incontinence"

Guest Expert Faculty, Nordic Conference on Ob/Gyn, Oslo, Norway, 6/2/99

Guest Speaker, Arkansas Section of ACOG, Little Rock, Arkansas, 6/4/99: "Medical Management of Urinary Incontinence" and "Laparoscopic Surgery for Urinary Incontinence"

Guest Speaker, for the University of Kansas -Wichita Department of Ob/Gyn, 6/19/99, the Daniel K. Roberts Ob/Gyn Update: The Female Patient: Contemporary Issues: "Pelvic and Reconstructive Surgery, Theory and Practice, I & II"

Central Travel Club meeting, Butte, Montana, 7/28-30/99

International Continence Society Meeting, Denver, Colorado, 8/21-25/99

NIH Terminology Workshop for Researchers in Female Pelvic Floor Disorders Meeting, Bethesda, Maryland,

8/26-27/99

Faculty, Pacific Northwest Review of Ob/Gyn Course, Portland, Oregon, 10/1-2/99: "Utero-sacral Suspension for Vaginal Vault Prolapse and "The Paravaginal Repair"

ACOG District VII Annual Meeting, Charleston, South Carolina, 10/3-5/99: Annual Lonnie Burnett Video Seminar presentation

Annual Meeting of the American Uro-Gynecology Society, New York City, 10/13/99

Annual Meeting of the Society of Gynecologic Surgeons, New York, 10/14-17/99

Advanced Pelvic Floor Surgery Course, (S&W) (Program Director), Salado, Texas, 10/24-25/99: "Anatomy of Pelvic Support", "The Defect Approach to Reconstructive Surgery", "Complications of Incontinence Surgery", "Retropubic Anatomy and Repairs for Urinary Incontinence", and "Management of Mixed Incontinence".

Speaker, Armed Forces District ACOG meeting, San Antonio, Texas, 11/4/99: "Compartmentalization of Pelvic Suport Defects"

Liaison Committee in Ob/Gyn, Chicago, Illinois (member), 11/30/99

Associate Board Examiner for the American Board of OB/GYN certification exams, Chicago, Illinois, 11/8-12/99

12th Annual Wayne F. Baden Lectureship (Program Director), S&W, 12/9/99

Program Director and Faculty, 13th Annual Pelvic and Vaginal Surgery Course (S&W/TAMU), San Antonio, Texas, 12/10-11/99: "How to Pick an Operation for Urinary Incontinence" "Pathophysiology of Enterocele, Rectocele and Cuff Prolapse". Coates: "Evaluation of Urinary Incontinence", "Medical Management of Incontinence" and "Abdominosacrocolpopexy"

NIH Terminology Workshop for Researchers in Female Pelvic Floor Disorders, 12/13-14/99, Bethesda, Washington DC

1998:

Faculty, Pelvic Reconstructive Surgery Course, Atlanta, Georgia, 1/12-13/98

24th Annual Society of Gynecology Surgeons meeting, Lake Buena Vista, Florida, 2/28-3/4/98

Faculty, Pelvic Reconstructive Surgery, Northeast Mississippi, Tupelo, Mississippi, 3/20-21/98

69th Annual Meeting, Texas Association of Obstetricians and Gynecologists/Texas Section ACOG, Dallas, Texas, 3/26-27/98, member, Executive Committee

Speaker, St. Paul Medical Center, Dallas, Texas, 3/28/98: "Enterocele" and "Management of the Anterior Segment'

Consultant Surgeon, French Society of Vaginal Surgeons, 4/1/98, Marseilles, French

Guest Lecturer to University of Oklahoma Residents, Austin, Texas, 4/25/98

Program Director and Faculty, Advanced Pelvic Surgery Course, Salado, Texas, 5/4-5/98

American College of Obstetricians and Gynecologists Annual Clinical Meeting, New Orleans, Louisiana, 5/9-11/98, Chair, Texas Section ACOG

Faculty, Course on Advanced Pelvic Surgery, San Antonio, Texas, 5/21-22/98

American Urogynecologic Society Research Retreat, 6/11/98

1st International Consultation on Incontinence, Monaco, 6/26-7/1/98, Subcommittee Chairman, Physical Examination Committee.

Visiting Professor, Royal College of Obstetricians and Gynecologists, London, England, 7/6-9/98: "Planning Pelvic Reconstructive Surgery" and "The Vaginal Approach to Vaginal Vault Prolapse". Also served as Gust Master Surgeon to St. Georges Hospital, London and Princess Anne Hospital, Southampton

OB/GYN Central Travel Club, Billings, Montana, 9/10-11/98

Society of Gynecologic Surgeons Postgraduate Course in New York, 9/24-26/98

Guest Speaker, 10th Annual Pelham P. Staples, Jr., M.D. Practical Update in Obstetrics and Gynecology, Fort Worth, Texas, 10/10/98: "Pathophysiology and Surgical Correction of Urinary Stress Incontinence", and "Anatomy, Pathophysiology and Surgical Correction of Vaginal Prolapse"

Post Graduate Course Faculty, Surgical Management of Pelvic Organ Prolapse, Central Association of Obstetricians and Gynecologists, Kansas City, Missouri, 10/16-27/98

American College of Obstetricians and Gynecologists District VII Meeting, Birmingham, Alabama, 10/26-27/98 (Chair, Texas Section ACOG)

Program Director and Faculty for Advanced Pelvic Floor Surgery course, (S&W/TAMU), Salado, Texas, 11/2/98: "Anatomy for the Gynecologic Surgeon - Clinical Applications", "Pathophysiology of Enterocele and Prolapse of the Cuff", "Vaginal Repair", "Rectocele", and "Overview of Surgery for Urinary Incontinence"

Executive Committee Meeting, American Urogynecologic Society, Washington, DC, 11/11-14/98

Associate Board Examiner, American Board of Obstetrics and Gynecology oral exams, Chicago, Illinois 11/16-20/98.

Baden Lectureship in Gynecology, Scott & White Hospital, 12/3/98

Course Director and Faculty, S&W/TAMU Update In Pelvic and Vaginal Surgery Course, San Antonio, Texas, 12/3/98: "Anatomy for the Pelvic Surgeon", "Postoperative Care of Patients With Urinary Incontinence", "Complications of Incontinence Surgery", "Pathophysiology of Enterocele, Rectocele and Cuff Prolapse"

1997:

Visiting Professor, University of Hawaii at Manoa, Honolulu, Hawaii, 1/7-11/97

Faculty for the 6th Annual Controversies in Women's Health Care Course (TAMU/S&W), Cancun, Mexico, 2/5-8/97: "Review of AHCPR Guidelines for the Evaluation of Urinary Incontinence", "Complications of Incontinence Surgery", "Retropubic Space Surgery for Urinary Incontinence"

23rd Annual Society of Gynecologic Surgeons meeting, New Orleans, Louisiana, 2/24-25/97. Discussant at scientific session.

Guest Speaker, Stanley F. Rogers Symposium on Recognition of Pelvic Support Defects and Restoration of Functional Anatomy, Columbia Woman's Hospital of Texas, Houston, 3/21-22/97: "New Classification System for Pelvic Support Defects", "My Technique for Posterior Repair", "Transvaginal Approaches to Anterior Defects", and "Transvaginal Repair of Uterovaginal Prolapse"

Faculty (and Executive Council Member) 68th Annual Meeting of the Texas Association of Obstetricians and Gynecologists/Texas Section ACOG, Austin, Texas, 4/16-18/97: "Management of Vaginal Cuff Prolapse and Enterocele"

Speaker, 3rd Annual Scientific Session of the Annual Clinical meeting of the American College of Obstetricians and Gynecologists, Las Vegas, Nevada, 4/28-29/97: "The Vaginal Approach to Urinary Incontinence Pelvic Reconstructive Surgery"

Speaker, Advanced Laparoscopic Training, Atlanta, Georgia, 5/30-31/97

American Urogynecologic Society retreat, 6/6-7/97

Guest Consultant, 1st International Continence Consultation on The Overactive Bladder: From Basic Science to Clinical Management, London, England, 6/27-28/97

Faculty, ACOG Bilingual Postgraduate Course on "Pelvic Floor Dysfunctions", Guadalajara, Mexico, 7/18-19/97 (Organized by the ACOG District VII, Mexico Section, and The Mexican Federation of Gynecology and Obstetrics, and The Guadalajara Society of Gynecology and Obstetrics), "Cystocele, Physiopathology and Diagnostic Approach", "Paravaginal Defect Cystocele, Retropubic Treatment Approach", "Paravaginal Defect Cystocele and Mixed Cystocele; Vaginal Treatment", and "Fecal Incontinence; Patient Evaluation and Treatment".

Faculty, ACOG Postgraduate Course in Pelvic and Vaginal Surgery, Jackson Hole, Wyoming, 8/20-23/97.

Faculty, Society of Gynecologic Surgeons Postgraduate Course, New York City, New York, 9/10-12/97: "The Defect Approach to Reconstructive Surgery", "Complications of Incontinence Surgery", "Retropubic Anatomy and Repairs for Urinary Incontinence", and "Management of Mixed Incontinence"

President: American Urogynecologic Society meeting, Tucson, Arizona, 9/24-27/97

Faculty, ACOG Annual District VII Meeting, San Antonio, Texas, 10/11-15/98, Presented the Lonnie Burnett: Surgical Video Seminar

Guest Speaker, Baptist Hospital/Middle Tennessee Ob-Gyn Society, "Fourth Annual Advances in Pelvic Surgery" program, Nashville, Tennessee., 10/23-25/97

Board Examiner, American Board of Obstetrics and Gynecology oral exams, Chicago, Illinois, 11/3-7/97

Program Director and Faculty, S&W/TAMU Advanced Laparoscopic Training Course, Salado, Texas, 11/17-18/97

Speaker, 3rd International Symposium B Stress Urinary Incontinence and Genital Prolapse, Munich, Germany, 11/28-12/5/97

1996:

Executive Committee Meeting, American Urogynecologic Society, Chicago, Illinois, 1/6/96

Speaker, University of Alabama Southern Medical Society Progress in OB/GYN meeting, Birmingham, Alabama, 2/1-2/96; "Clinical Evaluation of Women with Pelvic Support Defects" and "Vaginal Pessaries and their use in Pelvic Relaxation".

Speaker, Kiser Permanente OB/GYN Group, San Francisco, California, 2/5-6/96 "Assessment of Pelvic Support Defects"

American College of Obstetricians and Gynecologists, District VII, Advisory meeting, Austin, Texas, 2/23/96

Speaker, Society of Gynecologic Surgeons, Albuquerque, New Mexico, 3/3-6/96: "Incidence of Recurrent Cystocele After Anterior Colporrhaphy and Concomitant Transvaginal Needle Suspension Procedure".

Speaker, Advance Laparoscopic Training Course, Atlanta, Georgia, 3/8-9/96

Guest Speaker, State University of Suffolk OB-Gyn Society, New York, 3/12-13/96

Guest Faculty, The Cleveland Clinic Foundation, Advances in Female Voiding Dysfunction and Pelvic Disorders, Cleveland, Ohio, 3/15-16/98 "Clinical Evaluation of the Female for Prolapse and Lower Urinary Tract Dysfunction", "Vaginal Surgery for Vault Prolapse", and "Paravaginal Repairs".

Speaker, Urogynecologic Review Course on □Urogynecology: Incontinence and genital prolapse overview, presented by HealthOne, Keystone, Colorado, 3/28-29/96 "Assessing Genital Prolapse", "Paravaginal Repair", "Drugs and the Bladder", and "Surgical Complications".

Visiting Professor and speaker at the Society of Air Force Clinical Surgeons Meeting, San Antonio, Texas, 4/2/96: "Compartmentalization of Enterocele Repair (video)"

Speaker, Pelvic Surgery Course, Department of Obstetrics and Gynecology at University of Virginia, Charlottesville, Virginia, 4/11-12/96: "Clinical Experience of Paravaginal Repair" and 'Symptoms of Pelvic Relaxation" .

ACOG Annual meeting, Denver, Colorado, 4/29-5/1/96

Guest Faculty, University of Miami School of Medicine Henry Lansman Lectureship, Miami, Florida, 5/14-16/96: "Vaginal Paravaginal Repair and It□s Role in Management of the Anterior Vaginal Segment" and Update in Pelvic Surgery and Gynecologic Urology. Presented "Compartmentalization of Pelvic Floor Defects" and "Enterocele (a video)" and "Vaginal Approach to Prolapse and Enterocele Repair"

Executive Committee, American Urogynecologic Society, Warrenton, Virginia, 6/6-8/96

Guest Speaker, Mexican Urogynecological Society, Mazatlan, Mexico VII National Congress, 6/26-28/96

Guest Speaker, Society of Gynecologic Surgeons, New York City, New York, 9/11-14/96: "The Defect Approach to Reconstructive Surgery", "Clinical Evaluation of Urinary Incontinence", "Retropubic Anatomy and Repairs for Urinary Incontinence", "Complications of Incontinence Surgery", and "Management of Mixed Incontinence"

Guest Speaker, International Congress of Gynecologic Endoscopy, AAGL 25th Annual Meeting, Chicago, Illinois, 9/24-26/96. 'The Rectovaginal Septum Revisited: Its Relationship to Rectocele and Its Importance in Rectocele Repair", "Anatomy & Physiology", and "Surgical Therapy of the Pelvic Floor, Traditional Methods" "Urinary Stress Incontinence".

American Urogynecologic Society meeting, New Orleans, Louisiana, 10/4-7/96

Central Association of Obstetricians and Gynecologists, Houston, Texas, 10/16-19/96

Speaker for Women's Health Care Lecture Series on Incontinence and Prolapse presented by S&W Options for Health on 10/26/96: A Pelvic Relaxation..

Board Examiner for the American Board of Obstetrics and Gynecology, Chicago, Illinois, 11/11-15/96

American College of Obstetricians and Gynecologists District VII Annual Meeting, New Orleans, Louisiana, 11/17-18/96 (Chair, Texas Section ACOG)

Program Director and Faculty, S&W/TAMU Update in Pelvic and Vaginal Surgery Conference, San Antonio, Texas, 12/6-7/96.

Speaker, Advanced Pelvic Surgery Urogynecology Postgraduate Course, Scottsdale, Arizona, 12/12-13/96

MILITARY SERVICE:

U.S. Air Force, 1973-1975, Major, Medical Corps

04/11 rev.